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AGENT ORANGE LEGISLATION AND OVERSIGHT

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

ON

S. 1692, THE PROPOSED "AGENT ORANGE DISABILITY BENEFITS ACT OF 1987"; S. 1787, THE PROPOSED "VETERANS' AGENT ORANGE DISABILITIES ACT OF 1987"; AND AGENT ORANGE OVERSIGHT ISSUES

MAY 12, 1988

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AGENT ORANGE LEGISLATION AND OVERSIGHT

THURSDAY, MAY 12, 1988

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The committee met, pursuant to notice, at 8:02 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Alan Cranston (chairman of the committee) presiding.

Present: Senators Cranston, DeConcini, Rockefeller, Graham, Murkowski, Simpson, and Thurmond.

OPENING STATEMENT OF CHAIRMAN CRANSTON

Chairman CRANSTON. The hearing will please come to order. Good morning to you all. I welcome you to today's hearing of the Committee on Veterans' Affairs on Agent Orange-related research, oversight issues, and legislation—S. 1692, introduced by Senator Murkowski, and S. 1787, introduced by Senators Daschle and Kerry; and I welcome Senator Daschle as the author of that bill to the committee this morning.

We have a great number of witnesses scheduled to testify this morning, including representatives from the VA; scientific entities which have conducted or reviewed research related to the health effects of Agent Orange or other herbicides; representatives of veterans' service organizations, and, I would particularly like to note, eight witnesses who either are Vietnam veterans or are representatives of Vietnam veteran or Agent Orange organizations.

Since Agent Orange first came to public attention in the 1970s, I have been working to resolve the concerns raised about the possible adverse health effects arising from veterans' exposure to Agent Orange in Vietnam. These have been very emotional and controversial issues, and the inability to resolve them completely has undoubtedly contributed to a feeling on the part of some Vietnam veterans that they have not been treated fairly by the Nation for which they fought.

I am proud to have authored legislation that provides VA health care eligibility for Vietnam veterans exposed to Agent Orange and that mandates a comprehensive epidemiological study of the health of Vietnam veterans, but I feel that we must continue to work to ensure that all appropriate efforts are made to try to find answers to the questions that have been raised regarding the long-term health effects of Agent Orange exposure and to ensure that these veterans are treated fairly and compassionately.

It is my hope that today's comprehensive hearing will help move us toward those goals.

There is one aspect of this morning's testimony that I believe requires special attention. In the Vietnam Experience Study, the CDC has found that 14.7 percent of the Vietnam veterans have experienced combat-related post-traumatic-stress disorder at some time since their service and that 2.2 percent had this disorder during the month before their examination.

These results are the latest, and to this point the most detailed, findings that some Vietnam veterans have suffered and continue to suffer significant psychological problems related to their service in Vietnam.

I intend to determine this morning whether these findings are borne out by the extensive PTSD study that Congress mandated the VA to carry out 4 years ago and which is being carried out by Research Triangle Institute.

From the very outset of my time in the Senate in 1969, I have been concerned about this issue. Although there were many delays before the VA got started, it has taken some appropriate steps to respond to the needs of these veterans, especially through the Vet Center Program.

However, more effort is still needed in terms of increased efforts to provide a full range of care and treatment for veterans with PTSD, including specialized inpatient units; greater support for research into the disorder, a priority recognized by Congress just this month in sending H.R. 2616 to the President for signature; perfecting treatment methods; and ensuring better coordination and cooperation between those in the VA responsible for providing treatment and those responsible for adjudicating claims for benefits.

Our committee has already scheduled an oversight hearing for July 7 to consider these and other PTSD issues. That hearing takes on new urgency in light of the CDC findings.

I urge the VA to evaluate carefully these CDC findings, as well as the soon-to-be-released results from the VA's PTSD study, both in the context of submitting any proposals related to the future of the Vet Center Program, such as are called for in H.R. 2616, and generally as the agency seeks to meet the needs of Vietnam veterans.

I further urge the VA to be prepared, as soon as possible and certainly by the July 7 hearing, to respond in detail to the many findings and recommendations that the Chief Medical Director's Special Committee on PTSD has made in its four reports.

Healing the wounds of war must be the VA's primary responsibility, and the findings on PTSD again highlight one area that demands special attention in this regard.

I recognize that the issue of veterans' exposure to Agent Orange through their service in Vietnam is an emotional and divisive one for many Vietnam veterans, as well as for their families and others. I believe this hearing would not be complete—or fair—without providing them the opportunity to present first-hand their concerns about these issues.

I am sure that the result which we all hope for from the scientific studies is a finding that exposure to Agent Orange or service generally in Vietnam does not portend an increased risk of various diseases. However, if such risk does exist, we must see to it that our veterans are treated appropriately and fairly.

I hope that this hearing will provide a clearer picture of the overall state of science on this issue and will aid us in our efforts to grapple with this very complicated, divisive, intensely felt, and vitally important issue.

I will conclude in order to allow the maximum time for our witnesses by noting that I have a more detailed written statement which is available on the press table. I thank those witnesses who got the testimony to us 48 hours before the hearing as requested.

Before proceeding now, I would like to remind everyone that, since we have many, many witnesses today, I must ask that each witness limit his or her oral testimony to 5 minutes, so that we will have sufficient time for questions.

We will be using the red and green lights here this morning. When you see the red light, your 5 minutes have expired. I would greatly appreciate everyone's cooperation in observing the limit; and of course, each witness' prepared statement will be printed in full in the record of this hearing.

[The prepared statement of Chairman Cranston appears on p. 127.]

Chairman CRANSTON. Now, Senator Strom Thurmond, do you have an opening statement?

OPENING STATEMENT OF SENATOR THURMOND

Senator THURMOND. Thank you. Yes, I do. Mr. Chairman, it is a pleasure to be here this morning to receive testimony on the Agent Orange legislation.

Each of the bills before this committee today, S. 1692, introduced by the ranking minority member, Senator Murkowski, and S. 1787, sponsored by Senator Daschle, will provide disability compensation to Vietnam veterans exposed to the herbicide Agent Orange.

In the past, the issue of establishing a presumption of service-connection for veterans exposed to Agent Orange has generated a great deal of publicity and emotion. It is certainly one of the more difficult and perplexing issues with which this committee has dealt.

Accordingly, we must continue to ensure that this issue is approached in a sound yet compassionate manner. This committee and the Congress have approved related legislation on this matter in the 96th and the 97th Congresses.

In the 96th Congress, the Veterans' Health Programs Extension and Improvement Act provided for a large epidemiology study of Vietnam veterans exposed to Agent Orange. Later, during the 97th Congress, the Veterans' Health Care, Training and Small Business Loan Act provided medical care for Vietnam veterans for any condition which might possibly have resulted from exposure to Agent Orange. At the present time, there are numerous scientific studies which have been conducted to determine the effects of exposure to Agent Orange.

The results of these studies are mixed. Some have indicated a close link of certain diseases to Agent Orange, and others have not. The wait for definitive answers continues to frustrate all of us, especially Vietnam veterans and their families.

One thing, however, is certain. The resolution of questions relating to Agent Orange is complex. On the one hand, there appears to be some link between Agent Orange exposure and certain diseases listed in these bills. On the other hand, the link is not wholly supported by the entire scientific community.

I plan now to keep an open mind on this matter and intend to carefully study the testimony provided at the hearing. The Senate Armed Services Committee bill is up on the Senate floor and I am going to have to leave, Mr. Chairman. I will read the testimony later. Thank you very much.

Chairman **Cranston**. Thank you very much, Strom. Senator Daschle, one of the authors of the bills that are before us, with Senator Kerry. I want to call on Senator Daschle, who has demonstrated such a great interest in this matter.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM THE STATE OF SOUTH DAKOTA

Senator **Daschle**. Mr. Chairman, I want to thank you for your leadership and willingness to commit the time and attention to the Agent Orange issue this morning. I have an extensive statement that I would like to submit as my testimony, but I would like to make a couple of opening remarks if I could.

Until recently, the Government has consistently argued that exposure to Agent Orange will not result in any significant increase in illness. They point to the 1984 Ranch Hand Study, which they concluded was negative and actually gave reassurance to Ranch Handers and their families.

In February of this year, the Air Force issued an interim report on the Ranch Hand Study, in which they no longer concurred with that 1984 conclusion. They pointed out new evidence and drew different conclusions from those drawn in 1984.

This is a positive report now of an increase in birth defects, which have been verified, using a control group, an increase in skin cancers that cannot be explained by overexposure to the sun, and the fact that systemic cancers cannot be ruled out. The report also explained the problems in study methods for identifying exposure and concluded that dioxin is not exonerated as a causative agent of veterans' disabilities.

The VA Mortality Study, another important report, was released by the VA last fall. The VA Mortality Study found that Marine troops serving in an area sprayed heavily with Agent Orange had a 110 percent higher death rate for non-Hodgkin's lymphoma than their Army counterparts who served in less heavily sprayed areas.

In addition, the incidences of lung cancer among the Marines were 58 percent higher than those of the Army veterans. So, in the last year, Mr. Chairman, we have had two studies, both of which point even more conclusively to a relationship between diseases experienced by many veterans and their exposure to dioxin.

In cases of veterans with disabilities that are caused by enemy fire, this committee has a long history of being willing to commit the benefits of compensation to those veterans.

For the sake of argument, I am not going to compare Agent Orange victims to those veterans, even though their pain and injury is no less real than those who may have lost an arm or a leg. But I will compare Agent Orange victims to veterans with multiple sclerosis, or diabetes contracted within 7 years of service, or prisoners of war with spastic colons.

All of these veterans have been granted presumptions of service-connected disability, though many might find the scientific evidence linking their disabilities to service weaker than the evidence in the case of Agent Orange.

S. 1787 would presume that non-Hodgkin's lymphoma and lung cancer contracted within 25 years of service, both clearly link the scientific literature to dioxin exposure, are service-connected. Second, it would establish a procedure for identifying immune system disorders; and finally, it would require that the VA make a very careful effort to gather and analyze information on medical treatment of veterans' disabilities, which may have been caused by Agent Orange and other toxic herbicides.

Does the scientific evidence support the presumption in S. 1787? Numerous studies have proven that dioxin is an extremely toxic substance. Precise toxicity varies from species to species, but the evidence of harm is incontrovertible.

No one should interpret S. 1787, the bill that Senator Kerry and I have introduced, as a statement that research should stop. We continue to support research and greatly appreciate the Air Force scientists and many other scientists who have continued to examine dioxin effects.

But there is a time for study and more study, and there is a time for leadership. In the case of veterans exposed to Agent Orange, as in so many other cases, including veterans exposed to atomic radiation, science will never be able to dictate policy. That is our role.

And the question this morning—the overriding question, it seems to me—is: Are we so afraid of being wrong that we are unwilling to risk being right? That is the issue.

Public Law 98-542 specifies that in compensation cases, where there is reasonable doubt, the benefit of the doubt shall be given to the veteran. With the evidence before us supporting the claims of Agent Orange victims, it is hard to understand the VA's claim that this reasonable doubt standard has not been met. The policy choice is clear. Do we give the benefit of the doubt to the veterans or to the dwindling odds that their exposure to a chemical which kills animals in laboratories has had no effect on them?

With that, Mr. Chairman, I want to again thank you for giving me this opportunity; and I look forward to participating in the hearing this morning.

Chairman CRANSTON. Thank you, Tom, for a very powerful statement. We appreciate it very, very much.

At your request, a statement submitted by you from Mr. Joe Cole of Olympia, WA will be retained in the committee's files.

Now, we will hear from Senator Murkowski, the ranking minority member and former chairman of the committee, a friend of veterans and another author of one of the bills before us.

[The prepared statement of Senator Daschle appears on p. 129.]

OPENING STATEMENT OF SENATOR MURKOWSKI

Senator MURKOWSKI. Good morning, Mr. Chairman. I also want to welcome everyone to the hearing this morning.

When American troops entered Vietnam, we quickly realized that one of our enemy's strongest allies was the concealment offered by the foliage in the jungles of that part of the world. We deprived the enemy of some of that concealment by destroying it, and what we used was herbicides.

Between 1962 and 1971, we sprayed approximately 3.5 million acres with 100 million pounds of one of those herbicides, and that one is known as Agent Orange. It is estimated that the spraying was contaminated by over 360 pounds of a chemical called TCDD, usually referred to as dioxin.

Dioxin is a known toxin for laboratory animals. For over a decade, both Vietnam veterans and the Congress have been concerned that veterans may suffer from adverse health effects as a result of exposure to Agent Orange.

The hearing this morning, as you have indicated, Mr. Chairman, will serve two purposes. We will receive testimony from scientists, agencies, veterans' groups, and others describing what we do know and what apparently we do not know about Agent Orange and its possible effects on veterans.

We will also receive testimony on proposed legislation which would respond to the many concerns of veterans who served in Vietnam and may have been exposed to this type of herbicide.

This morning we are going to learn of the deaths and diseases suffered by Vietnam veterans. We will also hear of scientific uncertainty and, I expect, conflicting interpretations of scientific data.

The Congress cannot resolve that scientific uncertainty. That is really not our task. However, we can and must evaluate the scientific data which we have and the opinions as they evolve.

We can, and must, charter a responsible course of action which considers both the scientific uncertainty and the legitimate desire for speedy and definitive action.

If we act before the scientific case is complete, that does not mean we lack respect for the dedicated and skilled work of our scientific community. It does not mean that we believe the scientific effort is in vain or should be ended by any means.

By the same token, our failure to mandate compensation at the first call of the Congress does not mean that we are willing to ignore the human suffering while we wait for impersonal scientific investigations to grind to a conclusion.

Our task on this committee is to balance the conflicting demands of scientific rigor and human compassion. Our task is to decide when the information is sufficient to set a legislative course of action. When it comes to hard decisions, the data will never be perfect.

The course will never be perfectly clear. If it was, the decision would have been easy rather than hard and would have been made a long, long time ago.

That is basically why I introduced Senate bill 1692. This bill focuses on one disease, non-Hodgkin's lymphoma, and sets up a presumption of service-connection for Vietnam veterans who suffer from it.

Some may argue that the evidence implicating this disease is imperfect. That may be, but we can no longer ignore the many fingers that appear to be pointing in that specific direction.

Some may argue that the bill is too limited, that other diseases should also be included. Possibly so, but in the case of other diseases, the negative findings are much more numerous, the number of intervening causes much greater. To include such diseases, the Congress would run the risk of perhaps over-reaching or creating a bill which would not be enacted and which would raise false hopes rather than compensate our veterans.

I believe this hearing is critical to the legislative process on the issue. I await the opportunity to study the information as it is provided. I am pleased that the legislation which has been introduced by myself, as well as the bill offered by my two colleagues, Senator Kerry and Senator Daschle, has served as a mechanism to focus the attention of the Senate and the public on the issue.

I also want to welcome again all those in attendance. I am especially honored that we have Admiral Zumwalt, the former Chief of Naval Operations and Commander of Naval Forces in Vietnam, who will be testifying this morning in support of this legislation.

I thank you, Mr. Chairman.

Chairman Cranston. Thank you very much, Frank. We have a statement from Senator Spark Matsunaga, a member of this committee, which will appear in the record at this point.

[The prepared statement of Senator Matsunaga appears on p. 131.]

Chairman Cranston. Now, we will go to our first witness, the Honorable Thomas Harvey, Deputy Administrator of Veterans' Affairs, representing the Veterans' Administration. Tom is a highly-decorated Vietnam combat veteran, a former chief counsel of this committee when Senator Simpson was chairman, and a friend and valued advisor.

Tom, we welcome you, and we welcome your handsome and charming son, Duffy, to this hearing, his baptism of fire in affairs like this, and your wife, Kathleen Black, who is also with you here today. We welcome you.

STATEMENT OF THOMAS E. HARVEY, DEPUTY ADMINISTRATOR OF VETERANS' AFFAIRS, VETERANS' ADMINISTRATION

Mr. Harvey. Thank you very much, Senator Cranston and members of the committee, for giving me the opportunity to appear before the committee this morning to talk about what truly has to be one of the most difficult and most complex issues that faces those of you on this committee.

It is an issue that is fraught with raw emotion, fraught with anger, guilt, fear, and confusion. In many ways, Agent Orange has become a symbol of the entire Vietnam experience, and it is brought up with all of the passions that the entire Vietnam experience elicited from so many people here in this country.

It brings forth anger from those who have negative feelings about our involvement in that war. It brings forth guilt, guilt from those who failed to serve in the military, who fled to Canada, or who otherwise avoided military service by availing themselves of various types of deferments that were available at that time.

It brings forth guilt from some veterans who served in the military but, again through their own efforts or otherwise, possibly just good luck, managed to avoid having to serve in Vietnam. And it brings forth a certain amount of guilt also from some veterans who did serve in Vietnam.

You know, the fact is that the "tail to tooth" ratio in Vietnam, the number of support troops supporting those of us who were in the field, was very high. This is something that has been written about extensively, and I have seen estimates as high as 17 to 1 down to as low as about 8 to 1.

I talked with Bobby Muller one day, the founder of Vietnam Veterans of America. He said to me that he had figured out why we had lost the war in Vietnam; and then, facetiously, he said: "We didn't have any support troops there." He said that among all the Vietnam veterans he had talked to in the many years he has been active in this area, never once did somebody say: "I spent my tour in Vietnam in an air-conditioned warehouse at Long Binh working on a computer processing your finance voucher."

And those of us who served in the military know that a great number of people did that.

The issue of Agent Orange elicits fear from many. You know, the Vietnam veteran is now a middle-aged man. The average age of the Vietnam veteran is 41 years old. He is now on the upward slope of the bell curve of his mortality.

Health problems have begun to manifest themselves within the Vietnam veteran himself and among his friends. He has seen friends die of illnesses, generally not associated with the mortality of young men. It is upsetting; it is disconcerting, but it is a fact. That is just the way it is.

And the issue is fraught with confusion. Studies have been done. The Veterans' Administration has spent some $100 million plus that you have appropriated to us to support those studies, attempting to find the causes of various different diseases and connections between Agent Orange and those diseases.

The research has not come up with conclusions that many people have wanted to hear. The issue is, in fact, one that has been studied for years; and as we have not come up with those conclusions, one would have thought the results should have been greeted as good news.

From the original concern that Agent Orange was a time bomb ticking away inside of those of us who served in Vietnam, what we have seen is that Agent Orange—at least in the amounts that most of us may have been exposed to in Vietnam—does not seem to cause the health problems in man or in his offspring that originally was thought.

Mr. Chairman, may I just talk for a moment about my own background in the military because I think that I can bring a particular perspective to this issue. Following law school graduation in 1966 and my admissions to the bars of Indiana and Illinois, I entered active duty as an infantry officer.

I served on active duty for almost 4½ years. I volunteered for airborne training; I am a senior parachutist. I volunteered for ranger training, and I volunteered for service in Vietnam, where I served for 2½ years.

I have a map here of the Republic of Vietnam; and let me, if I may, show you where I served. Here was the 173rd Airborne Brigade. Here is the city of An Khe, generally in this area in here.

I spent about 1½ years as an adviser with a Vietnamese airborne division, largely in the area north of Tay Ninh City, which is straight north of Saigon, somewhat south of that area there. It is an area where Tony Principi served with the U.S. Navy.

I also spent time around Saigon in some of the different areas with the Vietnamese airborne division, which I advised, who were involved in protecting the capital.

I received the Silver Star from an episode that happened right about here, a fire base called Vicky, which was almost overrun in November of 1969. And I have a Purple Heart that I received when I was hit by shrapnel in an area right about here, when my Vietnamese airborne unit was on joint operations with the 1st of the 22nd Mechanized Infantry.

Mr. Chairman and members of the committee, I do share the concerns that other Vietnam veterans have expressed about the possible effects of exposure to Agent Orange. I can't tell you for sure that I was exposed; I have no recollection of being sprayed. But I did serve in areas of Vietnam where Agent Orange was used extensively.

When I was in the military, I had two principal concerns. One of them was the accomplishment of my mission; the second one was the welfare of my troops. I must say I have very similar concerns today as I serve as Deputy Administrator of the Veterans' Administration.

In my confirmation hearing 2 years ago, you asked for my commitment that I would be an advocate for America's veterans. I am and I try to do that, and I believe today that all of America's veterans are my troops.

Let me give you another personal comment, if I may. About 3 years ago, a friend of ours, Fred Downs, who is known to many of you, had a baby. Fred is a highly decorated Vietnam veteran—Silver Star, Purple Heart, he lost his left arm in combat in Vietnam. Fred is certainly no soft touch, no bleeding heart.

Fred said to me one day, "Tom, you can't imagine how much I love that kid." I understand what he meant. About 6 months ago, Cathie and I adopted a little baby, who is here with me today. He is a healthy little baby; he is right here and sleeping quietly.

I came home from a business trip last evening. I was in Phoenix; where I chaired a meeting of the Architectural and Transportation Barrier Compliance Board. I got home about midnight, and I woke him up accidentally, and I felt bad because I really love that little kid.

And I can understand how a veteran who has a child, who has been born with defects, who has any illness, who is sick, who is impaired in any way, must wake up every day and think to himself: "Maybe it is my fault." I understand and I have tremendous sympathy for people who have that feeling because I can certainly see how I myself would react to a like situation.

Mr. Chairman, let me make two points real quickly. The substance of what I would like to say about the legislation currently pending is in the prepared statement that was submitted to the committee.

One of them is that part of the rhetoric surrounding the Agent Orange issue is that the Veterans' Administration is doing nothing about Agent Orange; the Congress is doing nothing about Agent Orange. That is just wrong.

We have, at the behest of the U.S. Congress, conducted an extensive literature review. We are now working on the 12th volume of that literature review—all the science that has been done with regard to this subject matter.

We are actively involved with information sharing. The information that we come up with, we share with others who are interested in pursuing the Agent Orange issue.

We continue to fund research. We are funding our own research; we are funding research conducted by the Centers for Disease Control.

We operate under the aegis of a committee established by the Congress, the Advisory Committee on Environmental Hazards, chaired by Oliver Meadows, who is certainly his own man, as all of you who know Oliver are aware; and it is made up of some of the most preeminent scientists active in this area.

And we provide treatment, pursuant to the law, for veterans who themselves define the problems that they are suffering from as being tied to Agent Orange.

We have examined about 228,000 registry entrants for the Agent Orange Registry. We have provided about 28,000 episodes of inpatient care and about 1½ million episodes of outpatient care for veterans who feel that their problems are related to Agent Orange.

What we are not doing is paying monetary compensation. And we are not doing so because it has yet to be established that exposure to Agent Orange is causative of any of the problems these individuals suffer.

The second point I would like to make has to do with the Veterans' Administration reward system. You know, no one at the VA is rewarded for denying benefits to a veteran. All of us are compensated monetarily and psychically for providing the benefits that veterans have earned through service to their country.

Our job is to carry out the laws enacted by you in Congress. You enact the laws; you authorize our programs. You appropriate the funding for those, and we do our best to carry those out and to provide you with the best scientific information that we can to enable you to make informed judgments about the laws that you are going to enact.

In summary, Mr. Chairman, let me just say that I believe that the legislation currently being addressed by the committee is an attempt to respond politically to an issue that really does call for a scientific answer; and to adopt such an approach is bad politics, bad policy, and bad science.

It is bad policy because it keeps the myth of Agent Orange as a cause of a large number of problems alive, without the scientific evidence in hand to back that up.

It is bad policy because those who hope this will keep the Vietnam veterans quiet will soon find that it won't. Those who believe their problems or the problems of their children are caused by Agent Orange won't go away, just because some few get monetary compensation; and that really is what we are talking about here. We are not talking about health care.

It is bad policy because it calls into question the credibility of the entire VA compensation scheme. Taxpayers seem to me to be entitled to have the Veterans' Administration administer a program that is based on scientific evidence.

And it is further bad policy because it perpetuates the myth of veterans as victims; and that is just not so.

Mr. Chairman, it is bad science because the evidence to support it just isn't there.

Mr. Chairman, thank you for letting me appear before you this morning. I would like simply to do two things. One of them is to read into the record one sentence from a letter that was in our report to the committee on this legislation; and it summarizes pretty much what that report states.

It says:

> In our view, it is not sound public policy to make sweeping presumptions based on frustration or the lack of scientific evidence to support desired conclusions.

I would also like, if I may, Mr. Chairman, furnish the committee with two things. One of them is a letter that the Administrator of Veterans' Affairs, Tom Turnage, sent to Senator Kerry on April 14, responding to an article entered by Senator Kerry into the Congressional Record.

And I would also like to furnish an article from Discover Magazine, dated April 1988, by Barry Toggs, entitled "Unmasking Agent Orange." It is the least histrionic of the articles I have read on this subject and, I think, does give a fair and balanced picture of this very, very difficult and complex issue.

Thank you very much, Mr. Chairman and members of the committee.

Chairman CRANSTON. Thank you, Tom, for that very interesting and unusual testimony. At this point, I want to yield to Senator Alan Simpson, our former chairman. And then, I am going to ask Tom Harvey to step aside temporarily because another witness has to leave shortly; and we want to give him an opportunity to testify. Alan?

[The prepared statement of Mr. Harvey appears on p. 159.]

OPENING STATEMENT OF SENATOR SIMPSON

Senator SIMPSON. Thank you, Mr. Chairman. I am very pleased to be here on this tough issue again, in these presumptions of service-connection with Agent Orange. Mr. Chairman, you will remember that you and I worked and have worked—and it has been a great personal pleasure for me to work with you—both as ranking member and then as I served as chairman and you were ranking member.

I remember the anguish we both had in this area of Agent Orange. And I remember so distinctly and ever more clearly the hysteria that you and I were confronted with when we had to deal with Agent Orange and dioxin—the emotion and the fear and the guilt and the whole works that unfortunately make this place hum.

It is pretty tedious to me. I have said it before, and I will say it again and again and again; I don't care how repetitive it is. We either pass or kill a bill in this place due to the depth of emotion, guilt, fear, or racism. It is a hell of a place to work.

But somebody has to come along and breathe honesty and truth into the system, and I feel that you and I did that. I will pound our backs—yours harder than I would mine—because we passed a bill of the U.S. Senate by 95 to 0; and I remember that very well, too, because we said you had to use sound medical or scientific evidence.

That wasn't enough. That wasn't enough for those who love to gin it up and keep it cooking. I will be damned if I know yet what their full agenda is unless it is just a continual scab picking contest to see how long it takes us to forget Vietnam.

Nobody is going to forget Vietnam. That is why we are paralyzed in Central America.

But I will tell you that I get awful tired of docudramas; either make them "docus" or make them "dramas." I get tired of the movie directors; I get tired of looking at the stuff which is ginned up by people who never were in Vietnam.

I asked one fellow once, "What was the purpose of that docudrama?" He was a very noted man. He said, "We had to show that, the ticking time bomb, the direction of the whole works." So, I said, "What were you doing during Vietnam?" He said, "That is none of your damned business." I said, "Yes, it is."

He said, "I am not going to tell you." I said, "I have a hunch you were probably the guy carrying the Viet Cong flag around on some little campus somewhere in America." He said, "Where did you find that out?" [Laughter.]

Senator SIMPSON. I said, "Well, I did my research, too." And so, there he is spending the rest of his life expiating his own sins and guilt for missing out and playing the game on the other side while guys like Tom Harvey and Tony Principi were over there doing it. So, I tire of it. Put me down on record.

As I have said before, I served 2 years in Germany in the era of the Army of Occupation and never considered that I did a thing. I just felt that was what we were supposed to do.

There are 27 million veterans. I note that a lot of them have never even been overseas. I have been through all that one before. Some of the members served under a year; we give them every benefit we give a combat veteran.

Now, we plaster 41 laws on the books of presumptive disease, diseases that are contracted by every single citizen in the United States. Somebody is going to have to sober up, and I am going to stay right in it. I realize fully the political hazard of it.

I have taken on the DAV before, and I will take on the DAV again. When you see their chief administrative officer making over $220,000 and giving me the business, then, you know, I will keep scrapping. All you have to do is go look at the record. So, I have been there.

I will tell you, Tom, that that was a very powerful statement. I know you and so does the chairman—a very steady and professional man. You were chief counsel and staff director of this committee; and I don't know anyone who fights harder for veterans.

It is good to have a breath of fresh air from people like you have been there and earned a Silver Star and a Purple Heart, instead of people who have never been there and just give us all the stuff that we have to swallow about that war.

You know, maybe we ought to start tacking our credentials on the wall. If you are a veteran, where did you serve? Where were you? Were you ever in the service? The debate as conducted on the floor of the House and the Senate oftentimes is by people who have never been in anything.

So, let's get our credentials out. I thought mine were kind of embarrassing when I was in, but they are not compared to half of them—probably pretty impressive. They are surely more impressive than movie directors and docudrama producers.

So, knowing you as I do and knowing Tony, and my own chief of staff, a combat veteran who was a helicopter pilot who hauled a lot of people off of that green earth of Vietnam; and maybe at some point—and here is a good chance—this is the start of what could be sanity; and that is to say that we do require a cause and effect. We do require sound medical and scientific evidence.

That is our job, not to just sit here and gin it up. On another committee which I sit on, the Committee on Aging, our job is not just to hold hands and get hysterical; it is to do something, to see that the budgets of the United States meet the requirements of the people of the United States.

So, I really commend you; as we do this exercise, which I thought the chairman and I at one time had put to bed, but we can't put it to bed. There have been more studies; as you said, you can get a hernia hauling around the stuff about dioxins, just as you can get a hernia hauling around all the stuff about radiation. But that is not enough around this place, not with creative staff at full tilt.

So here is a bill that springs from frustration, pressure, and keep pushing, keep pushing, keep pushing. Run down to the old newspaper and slip them another article. Look at the one this morning. The headline is all the same old stuff:

> Vietnam veterans are far more likely to suffer from depression, anxiety, and alcoholism, than veterans who served elsewhere, according to a comprehensive Federal study released yesterday.

That is paragraph one.

And the whole rest of the article isn't worth a whit, because it says in most respects the physical health of both groups was identical; that is right in the next part. They had hearing loss and low sperm counts; that is what they found, and nobody knows why that is.

But despite all this fact, the Vietnam veterans have reported twice as many physical illnesses as those who did not serve. They found "in most respects, the physical health of both groups was identical." That is what we have always found; what is new? And then this one—this is this morning, The Washington Post:

> Common stereotypes of Vietnam vets as mentally disturbed and socially maladjusted, it seemed important to point out that, in the vast majority of cases, the facts do not support that view.

That is what we have always said. And meanwhile, the old pressure and the frustration keep kicking us down the road like a rock in a rough creek.

And then we go to the point that Vietnam veterans' groups reported their children had birth defects at the rate of 65 per 1,000 compared to 50 per 1,000 for the veterans who served elsewhere.

Hospital records show a much lower rate of 29 per 1,000 compared to 24 per 1,000, according to the CDC. That is right. I believe that.

There it is. This is the same margin. And then they said that they were not certain how to explain the large difference between health problems reported by Vietnam veterans and the problems actually found upon examination. Well, why not?

They go to the movies, and they see docudramas. If I had been in that war, I would have been down on the registry every day of the year because, if I had hyperventilation or dizziness or high blood pressure, I would do that.

But unfortunately, the human condition goes along with things like depression and hyperventilation and anxiety; and that can be caused by a lot of things in life when you are 34 or 41 or 44 years old.

It can be caused by a ruptured and cracking marriage. It can be caused by a kid who is on dope. It can be caused by a parent who is off the rails. That is life. It doesn't have anything to do with whether you were in the service or not; and if it does, we handle that through the VA.

So, maybe we will all sober up around here; and thank heaven, we have a chairman who at least listens, because these are not railings of some former chairman.

This is the truth, and it can't come any clearer than it comes from Tom Harvey, a decorated veteran of Vietnam, who spent 2½ years over there and is not a walking time bomb; or Tony Principi, who sits at this committee table, who is not a walking time bomb; or my chief of staff, J.O. Ratliff, who is not a walking time bomb. They get tired of this crap, and so do I.

Chairman CRANSTON. Thank you, Alan. Tom, if you would stand aside a minute, we have Don Newman, who is the Chair of the Agent Orange Working Group of the Domestic Policy Council, who has another early engagement. We want him to come before us at this point. If you would please begin, because I know you have to leave shortly after 9 a.m.

I do want to stress that, from now on, we are going to try to stick to the 5-minute rule. Otherwise, this hearing will not end until next week.

STATEMENT OF DON M. NEWMAN, CHAIRMAN, DOMESTIC POLICY COUNCIL, AGENT ORANGE WORKING GROUP, ACCOMPANIED BY DR. JAMES O. MASON, DIRECTOR, CENTERS FOR DISEASE CONTROL

Mr. NEWMAN. Thank you very much, Mr. Chairman, Senator Simpson, and Senator Daschle. It is a pleasure to appear before you this morning. As the chairman has indicated, I chair the Agent Orange Working Group and have done so for the last 2½ years.

As you know, since 1979, the working group has served a coordinating role within the Government. In addition to facilitating discussions among Federal agencies and departments regarding Agent Orange research direction, it has assured scientific peer review of protocols and subsequent studies.

I am happy to represent an administration that has focused at the highest levels of Government research on the health of Vietnam veterans. I bring good news. After almost 10 years of effort and the expenditure of $90 million on scientific research of veterans several agencies, we can see the light at the end of the tunnel.

Today, we share with you conclusions based on good science which will give us, the Congress and Vietnam veterans cause to be reassured that their service in Vietnam and possible exposure to Agent Orange are not resulting in adverse health affects.

The Veterans' Administration, the Department of Defense, the U.S. Air Force, and the Centers for Disease Control will provide you details of the status and findings of the key studies over which the Agent Orange Working Group has had oversight.

They are the Department of Defense Ranch Hand Study by the U.S. Air Force, the CDC Vietnam Experience Study, the CDC Study of Selected Cancers, the CDC Agent Orange Study, and the VA Mortality Study, and other related studies.

The key point I wish to make today is that, in the studies which have come to conclusion, we are seeing no cause/effect relationship between service in Vietnam and possible exposure to Agent Orange and adverse health.

The studies concerning the ground troops show little or no increase in dioxin levels in these troops. As you will hear in other testimony, it does not now appear that the average Vietnam veteran is at risk from Agent Orange exposure.

Scientific evidence does not support the claim of major increases in ill health caused by exposure to Agent Orange. I, therefore, agree with the position taken by the Veterans' Administration in opposing the enactment of Senate bill 1692 and Senate bill 1787.

It is not sound public policy to make sweeping presumptions such as those in those bills, which appear to be based, understandably, on frustration or the lack of scientific evidence to support the desired conclusions.

I regret that I have another meeting to attend, as the chairman has indicated; but Dr. Mason, who at one time acted as chair of the Agent Orange Working Group, has my full confidence and can answer the scientific questions for me. With him is also Dr. Vernon Houk, the former chair of the Agent Orange Science Panel.

Additionally, Dr. Peter Beach, the Executive Secretary of the Agent Orange Working Group, can answer any questions on the historical nature.

Thank you very much, Mr. Chairman.

Chairman CRANSTON. Thank you. I would like to ask you a few questions before you have to leave.

Mr. NEWMAN. Yes, sir.

[The prepared statement of Mr. Newman appears on p. 196.]

Chairman CRANSTON. First, what relevance do you believe the Kansas study of agricultural workers has with respect to veterans' exposure to Agent Orange in Vietnam?

Mr. NEWMAN. I am sorry, Mr. Chairman, I did not hear that.

Chairman CRANSTON. The Kansas study of agricultural workers—are you familiar with it?

Mr. NEWMAN. Yes, sir.

Chairman CRANSTON. What relevance does it have to the veterans of Vietnam?

Mr. NEWMAN. The study would reflect the dioxin levels in the blood of workers that had been exposed to dioxin or Agent Orange and would seem then to correlate, with any comparable dioxin levels in the veterans in Vietnam who had been exposed to Agent Orange.

Chairman CRANSTON. What differences in the exposures reported to be present in the Kansas study and the nature of the exposure to Agent Orange in Vietnam would be significant regarding Vietnam veterans exposed to Agent Orange?

Mr. NEWMAN. One of the things that surprised us, Mr. Chairman, was that a little over a year ago we thought that we were going to be able to tie off the study because the determination of dioxin in the blood was so complicated. It wasn't until a year ago that we were able to develop a blood test whereby dioxin levels to the point of one per quadrillion were able to be determined, which was a breakthrough in the science.

Chairman CRANSTON. It is my understanding that no dioxin was involved in the Kansas study.

Mr. NEWMAN. May I have Dr. Mason join me at the table?

Chairman CRANSTON. Yes.

Dr. MASON. In the cancer study, I believe you are alluding to it being exposure of agricultural workers to 2,4-D, which is a different herbicide. And in that study, they showed that those farmworkers who were exposed to 2,4-D had an increased incidence or prevalence of non-Hodgkin's lymphoma.

I think, in the application of that to Vietnam, there are some difficulties, although as a principle it is something we need to look at; but first, we are talking about a different substance, 2,4-D versus Agent Orange. That is point one.

Point two is that we know that even in Vietnam veterans who actually sprayed or mixed Agent Orange, there is no question about their exposure. The Air Force study shows that conclusively, while it is very much more difficult to show evidence of exposure for the ground troops.

I think if you look at the Kansas study, you are talking about people who are more equivalent to those who were actually involved in spraying and mixing pesticides, versus ground troops. So, I think there are a number of significant differences that one needs to be aware of if one is going to extrapolate directly from the Kansas study to the Vietnam experience.

Chairman CRANSTON. Dr. Gasiwiecz, of Rochester, NY, in his written testimony for today's hearing, suggests that in light of the "consistent findings on all experimental animals yet examined regarding the toxic effects of dioxin, and since parent studies on humans are of limited use," we should rely on the animal data. My question for you is: Is the animal data so clearcut; and, if so, why isn't it used to conclude that dioxin is associated with adverse human health effects?

Mr. NEWMAN. I would have to beg the examination and the concentration of the dioxin that was used in those experiments, Mr. Chairman. There is a certain toxicity level for almost anything in the world, and the percentage of exposure is very critical to making a statement like that, sir.

Chairman **Cranston**. Would you take a look at his testimony and give us written comments on it?

Mr. **Newman**. Yes, sir.

Chairman **Cranston**. The VA Proportionate Mortality Study, the Kansas study, and the Western Washington study have each shown some excess of non-Hodgkin's lymphoma among those exposed to herbicides. Why isn't that enough to establish a scientifically-acceptable association between Agent Orange and NHL?

Dr. **Mason**. Although I think it is clear that these studies certainly suggest that there may be an association, this is exactly why the special cancer study that is being carried out by CDC was designed, to look at this issue specifically.

I don't believe we are going to know conclusively about non-Hodgkin's lymphoma among Vietnam veterans until the special cancer study is concluded because it was designed to look at one thing and one thing alone; and that is cancers that may be associated with dioxin exposure.

Chairman **Cranston**. Is there any scientific evidence linking lung cancer and dioxin exposure other than the VA's Proportionate Mortality Study findings with respect to the Marines?

Dr. **Mason**. I know of none. It was not even included within the special cancer study because cancer of the lung has never been associated with exposure to dioxin.

Chairman **Cranston**. Alan, do you have any questions?

Senator **Simpson**. Mr. Chairman, I just have something I would like to enter into the record so that we have it in the perspective, and I would like the article to be entered in the record as if read in total.

Chairman **Cranston**. It will be.

[The article appears on p. 201.]

Senator **Simpson**. And I would share it with others so that we have it in perspective as we talk about the Vietnam era veterans. I think it is very important; it is very short.

There are 8,744,000 veterans who served in the Vietnam era; that is, from August 5, 1964 to May 7, 1975. That is our official designation. Of those, 3,403,000 served in the Southeast Asia Theater of Operations; and many of those might have been in the Philippines, in Okinawa and Thailand and never even lived in country.

Of those, 2,594,000 served within the borders of South Vietnam. Twenty percent of those were infantry, armor, or artillery units that regularly pursued and engaged in combat, 20 percent of that 2,594,000.

And 40 to 60 percent of those who were in the country were at least probably exposed to enemy fire on a regular basis. So, as we get to thinking about this group of veterans who are in the United States, 8,744,000, we have what we have in just about all wars. About 1 out of 5 who were in the combat theater were actually in direct combat.

That is true of World War I, World War II, Korea, and now assumed for Vietnam. So, as we get this continual pressure and continual hype and the hysteria that goes with this, let's remember how many of those ever actually heard a shot fired at them or who were actually ever involved in the intimacy of having dioxin on their bodies.

And we know, of course, the most frustrating study of all for all these people who continue to bang the drums is the Ranch Hand Study because those guys practically bathed in it. In fact, the way you got it out of the helicopter was to let it fly all over you; that is the way they did it. And none of those people have a single shred of physical ailment different from the veterans who were not exposed.

So, I just want to get that in the record, Mr. Chairman, and I thank you. I would ask just one question. You have seen veterans appearing here who, during their military service, were exposed to injuries and conditions. Certainly, all of us feel that those who have a causal connection with disease or conditions that develop later should have service connection; I have no problem with that. Who does? Nobody that I know. But today, the question of what constitutes a service-connected injury or illness is less scarce than it once was. Bullet wounds or bayonet wounds are one thing. The hazards of modern training grounds and the battlefield are quite another.

As Tom Harvey recognizes, all the VA wants to do is care for the veterans of the United States. That is why we have a budget of $28 billion, to care for those whose injuries or illnesses are attributable to their military service.

Because of an extraordinary network of benefits and veterans' programs, that is vividly what we do here for the sacrifices made by the men and women in uniform; but the program was designed to care for veterans disabled in the line of duty.

And the rules and regulations for this program are designed to make certain that no veteran's reasonable claim for disability resulting from military service is ever overlooked or ever ignored, and that is what we do.

So, here we are with this legislation that says, in effect, that there is no longer a need to produce any sound scientific or medical evidence of the connection between exposure and the disease; and that is all we are requiring now.

And one of these bills even makes the presumption nonrebuttable; that is, even if it can be proven that the veteran was never exposed to the herbicide dioxin during his or her military service, the disease is service-connected.

What do you see in the trend if we go that way? Not only veterans' matters, but in any other issue where we have a contention. It is a troubling thing, whether it is radiation, atomic veterans, or whatever it may be in the panoply of life.

Mr. **Newman**. I would like to respond to that, Senator Simpson, by just saying that I could not equal the articulate presentation that you just gave, indicating that we would open up the Treasury and that anyone would have access to it.

Senator **Simpson**. I thank you, Mr. Chairman.

Chairman **Cranston**. Senator Daschle, do you have any comments or questions?

Senator **Daschle**. Mr. Chairman, I try to hold back my frustration and my emotion because I don't think it serves a purpose here. A lot has been said that I take personally and that I will comment on personally later on.

The fact is that, when you see information, regardless of whether it comes from the Air Force or a VA study that says, for heaven's sake, that certain veterans, who probably were exposed suffer from a 110 percent higher rate of non-Hodgkin's lymphoma, that is not nothing. That is something.

If these veterans have a 58 percent higher degree of lung cancer, that is also something. Now, you are right. The worst thing that could happen would be for us to get emotional and to start laying charges that cannot be founded; but that, at least, would require this committee to say what is happening.

That is all we are asking. What is happening when you see statistics like that? Now, to draw false conclusions is one thing; but to look at these things without hysteria, without any kind of charges about who is at fault, and whether or not you served in Vietnam—for God's sake, why would that matter?

I think we ought to look at these things, and that is what we are doing this morning; and that is what this bill would allow us to do.

Now, the bill that we passed—that passed 95 to 0 here in the Congress—says simply that when there is a reasonable doubt, the benefit of the doubt shall go to the veteran—when there is a reasonable doubt.

When you have documented cases, though, of a 110 percent higher rate of non-Hodgkin's lymphoma and twice the rate of birth defects in the Ranch Hand children, I don't know what other conclusions one can draw, except that there is a reasonable doubt—not any conclusive proof, but we don't have that now for multiple sclerosis and for a broad range of diseases that have already been mentioned.

Let me ask a couple of questions because I know you have to go. Virtually every scientist we have asked, including Government scientists, has indicated that Agent Orange/dioxin cannot be exonerated as a causative agent in human illness.

Mr. Newman, are you formally disagreeing with that position? Are you saying that we don't really need any more studies in that regard?

Mr. NEWMAN. We have studies that are ongoing, Senator Daschle, but the conclusions from our large study would indicate that there is no cause/effect relationship between the illnesses claimed and the exposure to Agent Orange.

Senator DASCHLE. So, you are disagreeing with the statement that dioxin cannot be exonerated as a causative agent in human illness?

Mr. NEWMAN. We are still studying that question, sir. There are continuing studies.

Senator DASCHLE. Then, dioxin still could be a causative agent; you don't know?

Mr. NEWMAN. No, sir. It isn't quite that definitive. We have the results of $90 million worth of effort here that indicates there is no cause and effect relationship between illnesses claimed and the exposure to Agent Orange.

We are still continuing with additional studies. There are a couple of studies that are ongoing that we are still continuing to exhaust the question; but the results of the studies to date show there is no cause and effect relationship.

Senator DASCHLE. A toxicologist by the name of Ellen Silbergeld said that dioxin was in the Kansas mixture of 2,4-D. Are you saying that that is not accurate?

Dr. MASON. No, I am just saying that we are talking about Agent Orange, which was contaminated with dioxin and 2,4-D. The Kansas Study may have dioxin there; but their findings are in the operators and the sprayers of the pesticides. I think if there is something similar going on, then it will be picked up by the Ranch Hand Study that is being carried out by the Air Force because they have a specific group of people in which there is no question about their exposure.

They were exposed in the context of carrying out their military mission in Vietnam; and, as of this point, I am not aware of any conclusive findings that, even with high levels of exposure in the Ranch Hand personnel, that we can show that there was disease.

When you get to combat troops in Vietnam, we are talking about a totally different population where we cannot document exposure to dioxin except among those that were exposed through spraying, mixing, or handling. I am not saying that there were not some, but we haven't found a group large enough that we could even begin to study.

You might be able to apply the Kansas Study to what we are studying in Ranch Hands; but you can't take Kansas and apply it to ground combat troops in Vietnam because it is a totally different situation.

Senator DASCHLE. Let me just ask the same question of both of you, and this will be my last question. Public Law 98-542, as you all know, establishes that reasonable doubt be the standard for Agent Orange claims, that when there is reasonable doubt, the benefit of the doubt shall go to the veteran.

In your mind, what would it take to constitute not proof of Agent Orange related harm, but reasonable doubt?

Mr. NEWMAN. The key word there, I think, is "reasonable," sir; and the fact that we have spent all of this money—$90 million—and over a period of exhaustive years in studying at the pure scientific level and cannot establish a cause and effect relationship, I think, is reasonable doubt.

Senator DASCHLE. And the Air Force interim report has no bearing?

Mr. NEWMAN. I would have to see the report, sir.

Senator DASCHLE. You haven't seen the 1988 interim report?

Mr. NEWMAN. The Air Force interim report of February 1988? Yes. You will hear about that later.

Senator DASCHLE. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you very much. We appreciate your testimony.

Mr. NEWMAN. Thanks to you, Mr. Chairman.

Chairman CRANSTON. Tom, would you resume your position at the table?

Mr. HARVEY. Yes, Mr. Chairman.

Chairman CRANSTON. Tom, in your written statement, you cite certain concerns regarding the significance of the VA Proportionate Mortality Study findings with respect to non-Hodgkin's lymphoma. Could you elaborate on those concerns?

Mr. HARVEY. Yes, Mr. Chairman. Thank you for letting me touch on that. The VA Proportionate Mortality Study made a determination that there is a higher incidence of non-Hodgkin's lymphoma as well as lung cancer among Marines who served in the I Corps area of Vietnam, the very northern part of the country.

It does not find any consistency of that mortality rate among either Army troops who served in I Corps along with the Marines or among other military forces who served elsewhere in the country of Vietnam.

The study then states something along the lines of not knowing why that is. It indicates that further studies are necessary. There are a number of things that could possibly be a cause of illness. Agent Orange is one. Another is antimalaria medications. One medication was taken as a daily pill and the other one was taken once a week; it was a good-sized orange pill that made your stomach upset for a little while after you took it.

In each of the locations where I served during the entire time I was in Vietnam, I took both of those types of medications. So, as I said before, I share the concerns of people who fear that there may be problems that are lurking in their own future because of exposure to Agent Orange because I believe I probably was exposed to Agent Orange.

I share the same concerns if you want to define that problem as one caused by utilization of this other type of medication, which is a strong medication.

The other thing is that, on review by the Advisory Committee on Environmental Hazards, I am sure that Mr. Meadows and others from his committee, who will be testifying this morning, will address the specifics of this. What they suggested was that this study was one that indicated a need for continued study.

Chairman CRANSTON. Thank you. In your written statement on page 4, you state that the Proportionate Mortality Study was not accepted for publication by the "Journal of the American Medical Association". Do you know why it was rejected?

Mr. HARVEY. No, I don't. I do know that, immediately upon completion of that study, which was in February of last year, we made efforts to get it published in the "Journal of the American Medical Association".

Chairman CRANSTON. Is there anyone else from the VA who could tell us why it was not?

Mr. HARVEY. Dr. Lewis perhaps may have a comment on that.

Dr. LEWIS. We really don't know. We submitted it, Mr. Chairman, and we revised it pursuant to recommendations of the peer review group. We resubmitted it following that; it was rejected. We then submitted it to the Veterans' Advisory Committee on Environmental Hazards.

Early on there was a suggestion that the Veterans' Administration was trying to sit on that study, was trying to kill it, and was trying to keep that information from the public. Just the contrary. We were trying to get the maximum public exposure to that information.

Our concern was that, if we discussed it prior to publication, it would not be accepted for publication because it was no longer really news.

Chairman CRANSTON. What changes have been made in the text to be published in the "Journal of Occupational Medicine" from the version that was made available last fall?

Dr. LEWIS. I can't tell you that.

Chairman CRANSTON. Does anyone know that?

Mr. HARVEY. Dr. Kang, one of the principal authors of the study is here with me this morning.

Chairman CRANSTON. Would you come forward, please, to the table?

My question was: What changes were made in the text to be published in the "Journal of Occupational Medicine" from the earlier version that was available last fall?

Dr. KANG. There wasn't much change made. What changes there were, were pretty minor changes.

Chairman CRANSTON. Thank you. Tom, although excesses of two diseases were found among the Marines in that study, no such excesses were found among the Army veterans who comprised 80 percent of the study subjects. Have you been able to determine what accounts for those differences?

Mr. HARVEY. Not yet, and we are continuing to pursue that because obviously that anomaly is something that is of great interest.

For example, it is generally accepted today that smoking causes lung cancer. When you find lung cancer in a higher incidence among a group of individuals, one of the things that you have to do is take a look and see if you can figure out how many in the group are smokers. We were not able to determine that from the available medical records of the mortality study subjects.

Chairman CRANSTON. They don't have data on lung cancer, though, as I understand it.

Mr. HARVEY. No. We were not able to determine the smoking history.

Chairman CRANSTON. The abstract accompanying the release of the study, which did not examine Agent Orange exposure, stated that "although exposure to Agent Orange may be suspected, this study did not investigate possible etiologic factors for these elevated malignancies."

On what basis was the statement made that "Agent Orange may be suspected"? Who is responsible for making that, and does the VA still stand behind that statement, implying a link between the study's findings and Agent Orange exposure?

Mr. HARVEY. Quite frankly, I wish they had found a more felicitous way to phrase that. I wish that that had not been suggested as a possible link.

Chairman CRANSTON. Does the VA withdraw that statement?

Mr. HARVEY. I can't tell you, Senator, without having the document in front of me and looking at it and assessing it.

Chairman CRANSTON. Would you reply for the record on that?

Mr. HARVEY. Certainly.

[Subsequently, the Veterans' Administration furnished the following information:]

The statement, "Although exposure to Agent Orange may be suspected. . . ." was made by the researchers who conducted the Proportionate Mortality Study of Army and Marine Corps veterans of the Vietnam war. The statement was included in the abstract of the published study because Agent Orange was used in Vietnam and numerous claims have been made that this defoliant was the cause of the illnesses reported by some Vietnam veterans. The statement in no way implies the existence of any linkage between exposure to this chemical and those illnesses. Agent Orange was only one of the wide variety of environmental agents to which veterans were exposed during their tours of duty in Vietnam.

Chairman **Cranston**. On page 5 of your written statement, you indicate that the VA is conducting five followup studies to the Proportionate Mortality Study. What is the status of each of those studies, and when will they be completed?

Mr. **Harvey**. Senator, may I ask Dr. Larry Hobson to join me at the table to respond to that?

Chairman **Cranston**. Yes.

Dr. **Hobson**. The five followup studies included the update of the Vietnam Veterans' Mortality Study. In conducting that, the mortality data on Marine Corps veterans who died between the years of 1982—when the data collection for the mortality study was concluded—to the end of 1984 are being collected and reviewed.

Chairman **Cranston**. We want to know when each one will be completed.

Dr. **Hobson**. The analysis of this information, as I understand it, should be completed by the end of this calendar year.

The second one was the mortality analysis of Army veterans stationed in the I Corps area of Vietnam. That is almost completed. Its exact date depends on what time we can get the information from the very cooperative group in the Armed Forces that provide the data as to the point of service for each individual veteran.

The military medical review record for smoking has been completed and did not yield any results.

The PTF, the patient treatment file, review for non-Hodgkin's lymphoma is expected to be completed by the end of this year.

The Retrospective Cohort Mortality Study for the Marine Corps Vietnam Veterans is under way also. We are not quite sure when that will be completed, again because of the necessity of going through the military records and obtaining the specifics from them.

We do expect that to be completed, certainly, within the next 18 months or so. That is about the closest we can come.

I might say we are putting quite a burden on the environmental support group of the Armed Forces, and our sympathies are with them in their attempts to get the data to us promptly.

Chairman **Cranston**. Thank you. Tom, the VA began publishing comprehensive reviews of the scientific literature relating to the health effects of herbicide exposures back in 1981 and has updated them each year. Will the VA continue to publish those updates each year?

Mr. **Harvey**. Yes, Senator. We have published 10 volumes of that analysis of scientific literature. There are two more currently in print, and we would anticipate continuing to publish them for the foreseeable future.

I think obviously, from what we have heard this morning and what I am sure you will hear as the morning goes on, that this is a subject that warrants continued review, continued analysis, and continued study until more answers are available to us.

Chairman **Cranston**. I would like to ask you this for a written response. The DAV in its written testimony, pages 12 and 13, recommended: one, an archive be created of frozen blood samples of Vietnam veterans who believe they were exposed to Agent Orange, to be available over the long term for research; two, the VA dedicate sufficient funds for investigator-initiated pilot research studies of specific components dealing with the Agent Orange issue; and three, the VA engage in an active outreach program for Vietnam veterans to ensure that they are kept updated on Agent Orange issues.

Would you provide an evaluation of each of those suggestions for the record, please?

Mr. HARVEY. Let me tell you that some of the information we are getting from the Ranch Hand Study is a result of having blood samples frozen in 1982 when those initial studies were done. That is what gave rise to the information regarding the half-life of dioxin in the human body.

[Subsequently, the Veterans' Administration furnished the following information:]

The Disabled American Veterans recommended "the creation of an 'archives' . . . maintaining frozen blood samples of Vietnam veterans who believe they were exposed to Agent Orange." The suggestion was that the samples would be useful for subsequent medical research, presumably by analysis for dioxins.

To serve as a means of studying the fate of dioxins within the body, the most suitable donors are those veterans whose exposure can be documented, notably the Ranch Handers. Their blood is already being preserved for study.

If the intent of the "archives" is to determine the relation between dioxin level and specific diseases, blood can be collected when the disease is present and need not be "archived" beforehand. Any necessary blood from unexposed volunteers beyond that already assayed during the Centers for Disease Controls' study could also be drawn at the time of the research project.

It is difficult to see what purpose could be served by an "archive" of blood, especially one containing specimens from a self-selected group of persons. A randomly-selected sample of veterans whose blood was drawn for some unidentified future use would be expensive and difficult to justify, as well.

The VA has considered carefully the desirability and possible utilization of an "archive" of human blood specimens. To date no proposed purpose has been clearly shown to justify such an activity.

Since 1980 the VA has offered incentives to its scientists who elected to study some aspect of Agent Orange. Speedy consideration of such projects, called investigator-initiated research, was assured and funded as follows:

	Fiscal year—		
	1986	1987	1988 [1]
Number of projects	20	15	14
VA funding	$710,581	$649,626	$598,000
Extra VA funding	$163,768	$12,004	
Total	$874,349	$661,630	$598,000

[1] Estimate.

Several of these projects have now been completed. The VA has always believed that special research projects should undergo the same rigorous review and the same critical appraisal as any other biomedical research effort. This principle is still followed even though it may result in fewer independent projects on Agent Orange, its ingredient, or contaminants.

The VA, through a variety of communication approaches, is attempting to keep Vietnam veterans and the general public advised of the status of the various research/nonresearch activities in which this Agency is engaged in their behalf. During the past several years, for example, a series of informational brochures entitled *Agent Orange Review* describing VA Agent Orange-related activities and policies have been published and given wide-spread distribution within the VA for dissemination to Vietnam veterans visiting VA health care facilities and regional offices. The VA is continuing also, the publication of the *Review of Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins*, including lay language synopses of that publication and a series of monographs for the education of its professional health care staff.

The VA regularly advises the various chartered veterans' service organizations of the status of such activities to assist them in keeping their constituents fully advised of efforts in their behalf and of the status of ongoing and/or completed research and nonresearch projects in which this Agency is engaged. The VA also participates in various Agency and interagency committees concerned with the resolution of the Agent Orange issue including the Domestic Policy Council Agent Orange Working Group and its Science Panel and the VA's Advisory Committee on Health-Related Effects of Herbicides.

Mr. HARVEY. The other point about outreach, I think, is an excellent idea. I believe we are doing that right now. Our Agent Orange Projects Office has regularly published material for veterans, informing them of just what Agent Orange does.

We have a video tape that I believe is available through our system that gives information about Agent Orange and what it does and doesn't do and attempts to debunk some of the myths about that chemical.

Chairman CRANSTON. Thank you. I have a few more questions, but I have used 10 minutes; so I want to yield to Senator Simpson.

Senator SIMPSON. Mr. Chairman, thank you. I won't use my full 10 minutes. We do have a haunting schedule here; but knowing you, you will get it all in. You have a very fine blend there of people on both sides of the issue, and that is so critical.

I, too, share the view of the chairman about this difference when we come to this issue of the non-Hodgkins lymphoma; and this rather extraordinary figure for the Marines, and then the Army doesn't match at all. It is rather strange, and you have indicated it is unexplainable. Is that correct?

Mr. HARVEY. We have not yet been able to come up with an explanation for that. We are pursuing that, and we hope that we will have some further information. Senator Simpson, should it be determined at some time that there is a causative relationship, let me assure you that I would hope that the 240,000 people who work with me in the Veterans' Administration would be as committed as I am to making sure that the right thing is done for those who served with me in Vietnam.

Senator SIMPSON. I think it would be helpful for us if we had the analysis of troop locations, time periods, and spray patterns for those Marines. I assume they have that or will have that?

Mr. HARVEY. Yes, Senator. That map overlay that I had with all that material marked in orange was, in fact, where the spraying had been done.

Senator SIMPSON. Even though Senator Daschle is no longer here, I want to pay respect to him.

Senator DASCHLE. I'm back. He is a Vietnam veteran, and he has a deep respect for this body; and I have watched him work in the House on this issue with a deep commitment, deep passion, the same as I have. I guess it takes one to know one.

It is good to hear that we can address this in an honest way and without emotion. And it is very important that we hear what he is saying; and what he is saying is that this issue of non-Hodgkin's lymphoma and lung cancer is a disproportionate figure and percentage.

And it will be helpful to have that information as well as related to the Army.

I think the important thing here—and then I am going to conclude—is for the American people to know that we have spent about $100 million of their money on this one issue for how many years?

Mr. **Harvey**. We certainly were doing it when I was up here with you, Senator, in 1981; and we are continuing to do it today. And that $100 million you referred to is just money the Federal Government has spent on research on this issue; and others are doing research as well.

As you know, several States have Agent Orange commissions that are pursuing this research. The American Legion has also funded a research project.

Senator **Simpson**. And what is the number of studies? It is a huge number of studies from every known source, in the Government, out of the Government, private, medical.

Mr. **Harvey**. I can't tell you just the number of studies that have been obtained through the expenditure of those research funds; but we do have a 12-volume set of books analyzing the research that has been done on dioxin not only by our American researchers, but also by others throughout the world who are pursuing this as an item of scientific pursuit.

Senator **Simpson**. In my experience, I have never found the VA reluctant to come to grips with presumptive diseases, especially when we go to put some on the books here. There are 41 of them. Now, we had a bill the other day with regard to 13 more. The list now is 40 diseases now presumed to be service-connected; and then we added lupus to that. For former prisoners of war, we added three conditions.

We have the radiation compensation bill that added 13 diseases to the list of those that we presume to be service-connected.

But in that $100 million on studies, I want to clearly understand the conclusions that the VA has drawn in reviewing your testimony. Is there any present reasonable scientific and medical evidence to justify establishing a presumption of service-connection in this situation?

Mr. **Harvey**. No. There is not.

Senator **Simpson**. And, most importantly, and ever more importantly, if there were one shred or any essence of scientific or medical evidence in a veteran's individual case, could a veteran under current law—without changing one whit of the statutes—be determined to be considered as service-connected for non-Hodgkins lymphoma or lung cancer?

Mr. **Harvey**. Yes, he could.

Senator **Simpson**. He could be covered, and he is covered?

Mr. **Harvey**. He is covered. Yes, sir.

Senator **Simpson**. Why is it that the American public and those who propose this legislation miss that point? What is it that generates the scheme and the energy and the firepower to seem to think that an individual veteran with sound scientific and medical evidence to back him up is going to be treated unfairly in the Veterans' Administration?

Mr. HARVEY. Indeed, he is entitled to medical care within the system, even without an establishment of causal relationship to his military service.

Senator SIMPSON. Well, it is a tough issue. I thank you, Mr. Chairman, and I will conclude. You know, many suffer these diseases; and when they feel they are connected with exposure without question—and I know they feel that; and it is traumatic, and I am not denigrating the essence of the strength of their feelings.

But the compensation system is what we have to protect. That is our responsibility in the Veterans' Affairs Committee, to protect the compensation system for veterans; and it was intended to compensate those with conditions that could be scientifically and medically linked to service to this country.

And I urge that we not stray from that very reasonable requirement. That is where I anchor in.

Mr. HARVEY. Senator Simpson, let me just reemphasize the fact that we are doing things in this area. We are providing health care; we are doing research; we are doing analyses. And we are making an effort to come up with responsible recommendations to you and the Congress so that, should you decide to make the authorization, you will have the scientific basis to do that, rather than what is lacking at the present.

Senator SIMPSON. Thank you, and thank you again for your testimony. And coming from you, who is a heavily decorated veteran of that war, who served superbly for our country; it took a lot of guts for you to do that.

Mr. HARVEY. Thank you, Senator.

Chairman CRANSTON. Thank you, Alan. Tom, do you have questions?

Senator DASCHLE. Yes, I do, Mr. Chairman. Mr. Harvey, I do want to thank you for your statement.

Mr. HARVEY. This is a new and exciting experience for me here, Senator.

Senator DASCHLE. I want to congratulate you on your child.

I would like to ask you this. Senator Simpson asked you if there was any shred of evidence that could bring you to the conclusion that there is any relationship between Vietnam service and certain diseases, and you said "absolutely not." That was a quote—absolutely not.

In 1987, the VA issued its report; and I don't know how one defines "shred of evidence," but maybe you could just elaborate a little bit on your findings to the effect that certain veterans died from a 110 percent higher rate of non-Hodgkin's lymphoma and a 58 percent higher rate of lung cancer. Is that a shred of evidence?

Mr. HARVEY. Senator, you are referring to the VA Proportionate Mortality Study, and we addressed some of that when you were out of the room. I will just repeat the comment that I made at that time.

That study found that there is that higher proportionate mortality ratio for those two diseases among a particular group of people—the U.S. Marines—who served in a particular part of Vietnam; but it was not found among Army troops who served in Vietnam in other places in the country. The study then said there are a number of reasons why this could be. Agent Orange is mentioned and a couple other things.

I don't have the study here with me to refer to. And it also mentioned the possible utilization of drugs, particularly an antimalarial drug, which we took every day; and there is another antimalarial drug we took for a different type of malaria. We took that once a week.

During my entire time in Vietnam, I used both of those drugs religiously as prescribed. That is just another thing.

Another issue is smoking. Everybody knows that in the last 20 years we found that smoking is generally the cause of lung cancer. One of the things we attempted to do was to review the records of the people who had lung cancer who showed up in that study, and find out if they were smokers. We weren't able to do that. That was a dead end.

But I would hope that our scientists and our statisticians and those who are competent to do this continue to pursue this issue because I think there are a lot of shreds. We need to be working to pull those shreds together into a coherent whole.

I don't think it would be responsible for me to give my support to the legislation you have proposed, based on the fact that that whole hasn't been created yet.

Senator DASCHLE. What conclusive proof was there that brought the VA or the Congress to the conclusion that, if you contracted multiple sclerosis within 7 years of your time in service, you were then eligible for compensation? Or that if you have diabetes, that is a compensable disease? Or that if you were a POW and got a spastic colon, that was compensable?

Is there conclusive proof in those situations that led the VA to support the inclusion, for presumptive disability compensation purposes, of those diseases?

Mr. HARVEY. Not at all. I don't believe the VA supported that. Certainly, if you had asked for my opinion on that, I would not have supported any of those presumptions personally.

Senator DASCHLE. And you can understand how it is difficult to differentiate between those diseases and the situation where you say under Public Law 98-542 that, if there is a reasonable doubt, that that doubt ought to be given to the veteran rather than to the statistical evidence that may be inconclusive.

How would you define the difference? What constitutes not proving reasonable doubt?

Mr. HARVEY. Let me tell you, Senator, that there are a lot of people that I have worked with in the Veterans' Administration during the 1½ years or so that I have been there who create the culture in that organization to favor the veteran in every single decision that is being made. It is tested right straight through the system. People may dispute that because they have had decisions go against them.

But I will tell you the culture of the VA is that, whenever there is an opportunity, to favor the veteran.

Senator DASCHLE. I couldn't agree more, Mr. Harvey. I think that the VA, has generally demonstrated overwhelming support for the veterans. But in this case, could you specifically say what constitutes in your mind reasonable doubt—not proof.

It seems to me we are setting sort of a double standard here. Whether we like it or not, the law now says that in 41 cases and soon—as the Senator from Wyoming said—54 cases, we are going to have presumptive disabilities. We have set that into law.

Now, here we have one more; and obviously, some would debate the question. Where do you draw the line? The law says that, in this case, where there is reasonable doubt, we give the benefit of the doubt to the veteran.

How do you define—you and the top person in the VA—the difference between proof and reasonable doubt?

Mr. HARVEY. It is a balancing act. And if research continues to come and more research tends to tilt to the side of finding that there is a causative relationship, there is a point at which that balance tips; and you say there is now reasonable doubt.

Today, I just don't believe that is there; and I can't articulate that much more specifically than that. I can't tell you that there could be one particular thing; and I could tell you that the Ranch Hand Study, were they to come up with some conclusive indications that there is a causative relationship somewhere—just like that, I would say: Senator, I was wrong before; and I am here to tell you that I want to be here to support doing the right thing for these veterans. But it just isn't there yet.

[Subsequently, the Veterans' Administration furnished the following information:]

Public Law 98-542 provides, in part:

> It has always been the policy of the Veterans' Administration and is the policy of the United States, with respect to individual claims for service connection of diseases and disabilities, that when, after consideration of all evidence and material of record, there is an approximate balance of positive and negative evidence regarding the merits of an issue material to the determination of a claim, the benefit of the doubt in resolving each such issue shall be given to the claimant.

This language has been misinterpreted to mean that reasonable doubt must be applied in the development of policy applicable to claims generally or even to specific types of claims such as those based upon exposure to Agent Orange. Such an argument ignores the plain language of the statute which speaks in terms of "individual claims for service connection" not in terms of general policy. The inapplicability of reasonable doubt as it relates to policy is further demonstrated by the comments of Mr. Montgomery when the bill which became Public Law 98-542 was under debate in the House. Mr. Montgomery stated:

> What this legislation says is that the Administrator must give due regard to the need to maintain, unchanged, the doctrine of reasonable doubt as it applies to individual cases. What this legislation does not say is that the doctrine controls determinations made by the Administrator with respect to any of the diseases which are the subject of a rulemaking procedure pursuant to this legislation.

Even if we were to assume that it is appropriate to apply the doctrine of reasonable doubt to the development of policy, it remains my judgment that the weight of the scientific evidence does not even begin to approach an approximation. There have been one or two suggestive studies involving populations with characteristics significantly different than those of Vietnam veterans. However, the fact that the findings have not been found consistently gives one reason to question the results. Clearly, they would justify further research to shed more light on the correctness of the findings and that is the course that we are pursuing.

Senator DASCHLE. I have used all my time. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you, Tom. How many applications for compensation have been made by Vietnam veterans based on chloracne?

Mr. HARVEY. I am not sure, Senator, how many have been made based on chloracne. I think that the number is 28,000 that have been made based on exposure to Agent Orange, which would cover a number of different things. Very few cases have been found to be chloracne-related disease. That is transient, it appears and then tends to go away.

Generally, where there have been major dioxin spills, such as the case in West Virginia, generally there is a rash of chloracne immediately following that spill and then, months later, that clears up.

If I may, I would like to correct that for the record——

[Subsequently, the Veterans' Administration furnished the following information:]

The Schedule for Rating Disabilities (38 CFR Part 4) does not have a specific diagnostic code for chloracne so it would have to be rated by analogy to some other skin condition using diagnostic code 7899. Our records show that since 1978 a total of 19,299 claims were filed for compensation under diagnostic code 7899. It is not known how many of those claims were for chloracne. Among Vietnam era veterans our records further show that 251,925 claims for service connection for skin disorders have been allowed.

Chairman CRANSTON. How many have actually been proved?

Mr. HARVEY. Very few.

Chairman CRANSTON. Could you give us a number in writing?

Mr. HARVEY. Yes, sir.

[Subsequently, the Veterans' Administration furnished the following information:]

Chloracne would have been rated under diagnostic code 7899. Since 1978, the VA has approved 1,143 claims for unspecified skin disorders. In 1985, our data collection system was modified to permit designation of those cases in which compensaton was being paid for chloracne. There are currently nine such cases. In six of those cases there were medical records showing that chloracne arose during military service. In the other three there were post-service findings of chloracne that were held to have been caused by in-service exposure to Agent Orange.

Chairman CRANSTON. For what disease has the largest number of Agent Orange-based claims been filed?

Mr. HARVEY. I am not sure, Senator.

Chairman CRANSTON. Please give us that response for the record in writing.

Mr. HARVEY. Yes, sir.

[Subsequently, the Veterans' Administration furnished the following information:]

Unspecified skin disorders under diagnostic code 7899 constitute the largest single category of diseases for which Agent Orange-based claims have been filed. Service connection has been allowed in 1,143 such claims and denied in 18,806.

Chairman CRANSTON. Can you provide us with the number of Agent Orange related compensation claims broken down by disease and outcome of the claim? Do that for the record also.

Mr. HARVEY. All right, sir.

[Subsequently, the Veterans' Administration furnished the following information:]

From its inception, the Special Issue Rating System (SIRS), which collects data on Agent Orange ratings, was capable of recording diagnostic codes, whether each disability was service-connected or not, and the fact that Agent Orange exposure was the basis of at least one of the veteran's claimed disabilities. SIRS could not initially identify which disability was alleged to have been caused by Agent Orange exposure. This produced rather imprecise statistics such as 31,956 veterans have filed Agent Orange claims and those veterans have a total of 103,446 non-service-connected disabilities and 44,707 service-connected disabilities. In November 1986, SIRS was modified to permit designation of the specific disabilities alleged to have been caused by Agent Orange exposure. This allows us to report the information requested, the number of Agent Orange related compensation claims broken down by disease and outcome of the claim, but only with respect to data collected since November 1986. As there are over 300 diagnostic codes involved, the following figures are reported by body system:

AGENT ORANGE CLAIMS, BY BODY SYSTEM, SINCE NOVEMBER 1986

Body system	Service-connection	
	Allowed [1]	Denied
Skeletal	102	378
Muscle	18	30
Eyes	6	142
Ears	37	118
Systemic	10	415
Respiratory	26	348
Cardiovascular	23	173
Digestive	34	499
Genitourinary	11	310
Gynecological	0	9
Hemic and lymphatic	2	241
Skin	143	4,518
Endocrine	5	55
Neurological	18	437
Psychiatric	42	302
Dental and oral	3	21
Total	485	7,996

[1] Although service-connection was allowed for 485 disabilities that were claimed to be due to Agent Orange exposure, the determination of service-connection was generally based on other grounds such as medical records which showed the claimed disability arose during military service.

Chairman CRANSTON. I have a few questions for Dr. Art Lewis, and I wonder if he could come forward? Dr. Lewis is the Deputy Chief Medical Director. Art, can you give us the status of the study mandated by Public Law 99-272 on the health status of women Vietnam veterans?

Dr. LEWIS. Dr. Hobson probably has better information on it, but that study has been carefully reviewed, and it is out for an RFP. It is anticipated that we will start that study some time at the end of this year.

Chairman CRANSTON. I understand that the preliminary results of the PTSD and psychological problem studies, mandated by Public Law 98-160, has been farmed out to the Research Triangle Institute and that these results are nearly ready to be sent to Congress. Is that correct?

Dr. LEWIS. Yes, sir.

Chairman CRANSTON. When will the preliminary results be sent?

Dr. LEWIS. The preliminary results should be sent to Congress some time within the next 2 or 3 weeks.

Chairman CRANSTON. Can you tell us if what has been found in that study is consistent with the CDC findings that have been described in their statement on the prevalence of PTSD?

Dr. LEWIS. That study, if you will recall, is in two sections. The first is the preliminary study that you are talking about. A third of the number of veterans who will be evaluated in that study will be reported in the preliminary study.

I think that the early data would suggest that the percentage of cases of PTSD in Vietnam veterans is rather close to the number reported in the CDC study. I think it is important to realize, however, that that is preliminary.

It has not been carefully analyzed, and it represents a segment of the population which has not had any followup in terms of family, in terms of the number of controls who are non-Vietnam veterans. So, in essence, we are taking one particular segment of the population.

I think it is also important to point out that there is some difference in the method of sampling between CDC and the VA, but also in the population being sampled. My understanding is that the population that was studied by the CDC are all Army veterans who have served one tour of duty.

The VA study will include all branches of the service, males and females, and will not be restricted to one tour of duty. Again, the instrument that was used to survey the veterans in the CDC study, according to the information that I picked up from JAMA, is that an instrument called the "Diagnostic Interview Survey," (DIS), and the Minnesota Multiphasic Personality Inventory (MMPI), were used.

We have used not only the DIS study instrument, but we have also used an additional survey study developed by Dr. Terrence Keene, who is the Project Manager of the study, and also using the Mississippi scale for combat-related PTSD (M-PTSD).

The feeling of our group is that perhaps the DIS survey is not critical enough and that further studies have to be done.

Chairman CRANSTON. Basically, is the preliminary data similar?

Dr. LEWIS. Yes, the preliminary data would suggest that it is very similar, sir.

Chairman CRANSTON. Thank you. Would you stay at the table because I will get back to you? I want to get back to Tom.

Dr. LEWIS. Yes, sir.

Chairman CRANSTON. H.R. 2616, which is now at the White House awaiting the President's action, would preclude the agency from taking any action with reference to relocating any Vet Center until such time as the national plan is submitted.

Will the results of these studies be taken into account in the national plan?

Mr. HARVEY. I am sure they will be taken into account. I would hope, however, that as time comes along, we can bring some flexibility into that Vet Center Program. It is our hope that we can move the Vet Centers onto Veterans' Administration campuses.

Frankly, we started working on this when I was on the Hill up here in 1981. Here, 10 years later, we ought to be able to be flexible and more flexible than we have been in addressing that. One of the problems is that once you have a Vet Center at a particular location, it develops a constituency, it develops employees, and so forth.

And we would like the flexibility to move that facility quite possibly to another area where it is really needed more, even though the population of that Vet Center dries up in its original location.

Chairman Cranston. I want to get back to Dr. Lewis. You are involved in staffing for the new Environmental Medicine Office, which is combining the VA's administrative and research functions relating to veterans exposed to Agent Orange, radiation, and other environmental hazards. What is the current staffing for the office?

Dr. Lewis. That office, sir, has not actually been established. We propose to do that as an outgrowth of Congress mandating an Advisory Committee on Environmental Hazards. Our feeling is that the radiation problem has enough importance that it should be elevated to the status of an office along with Agent Orange.

We would propose initially to utilize the expertise of the radiology staff in the Central Office and in the field, added to the current members of the Agent Orange Project Office. That office has both a research wing as well as an administrative section.

Chairman Cranston. What special mandate are you referring to here?

Dr. Lewis. There is an advisory committee required by the Congress to look into both radiation issues as well as Agent Orange.

Chairman Cranston. Did it recommend the Environmental Office?

Dr. Lewis. No, sir. This was a departmental decision, to elevate the radiation issue to a higher status, rather than having it function as it is at present in the Office of Radiology.

Chairman Cranston. Would staffing for that office be greater than the staffing currently provided in the Agent Orange Projects Office?

Dr. Lewis. To the extent that we might add a radiologist, possibly yes. On the other hand, Dr. Hobson, who currently heads the Agent Orange Projects Office, has expertise in radiation matters and could provide direction in both of those areas, sir.

Chairman Cranston. How will the same number of people be able to handle an increased workload? Are they underworked now?

Dr. Lewis. I suppose they would tell you that they are, but I am not at all sure that I can answer that for you, sir. As I say, the original proposal was that we feel that we could do this initially with the current staff.

Chairman Cranston. The Agent Orange Projects Office is overstaffed now?

Dr. Lewis. No, sir.

Chairman Cranston. No?

Dr. Lewis. No. I thought that you said that they were overworked, and I said I am sure they would tell you that they are.

Chairman Cranston. My question was: Are they underworked? Do they have plenty to do? How will they do all these increased functions without an increased staff then?

Dr. Lewis. At this point in time, that operation is being done, as I indicated, out of the Office of Radiology in Clinical Affairs. It is done without any additional staffing, and it would be——

Chairman Cranston. You are talking about the environmental medicine, radiology, and all the others; that is all being done there?

Dr. LEWIS. The advice on radiation issues all comes out of the radiology department. Yes, sir.

Chairman CRANSTON. It seems to me that you are taking on a lot of new functions in that office without new personnel to handle it. Suppose you give us a detailed analysis of who will be doing what before you proceed?

Dr. LEWIS. I think it is fair to point out that this was a proposal that we sent over to committees of the House and Senate, to just indicate the direction in which we were——

Chairman CRANSTON. We are not quarreling with the idea, but we are questioning the staffing. Would you give us a written analysis of that?

Dr. LEWIS. Yes, sir.

[Subsequently, the Veterans' Administration furnished the information which appears on p. 171.]

Chairman CRANSTON. What use do you make of the information in the Agent Orange register?

Dr. LEWIS. I think Dr. Hobson can probably answer that better, sir.

Chairman CRANSTON. All right. The question was: What use do you make of the information in the Agent Orange register?

Dr. HOBSON. The answer to that is that the Agent Orange register was of more use to us in the early years before we had any clues as to the kind of diseases we might be looking at.

At the present time, its usefulness has diminished. This is not a scientifically based survey or epidemiological study. It is simply a register of people who have come to us saying that they want an examination to reassure themselves.

Chairman CRANSTON. Should it be used as a mailing list to provide information updates on Agent Orange issues?

Dr. HOBSON. We have used it in that way in the past. The problem is that the addresses that were given to us at the time of the examination have become outdated; and consequently, we would have to go to the post office and ask them for cooperation in obtaining more recent those addresses.

We did use it until such time that it became rather useless in that respect.

Chairman CRANSTON. Thank you. Frank, do you have any questions?

Senator MURKOWSKI. Very briefly, Mr. Chairman. I would like to refer to the out-of-court settlement that I believe occurred as a result of a class action suit brought against Monsanto and Dow. It was brought by a group of veterans, I guess, pretty much on their own.

And the out-of-court settlement was in the area of $180 million. Could you comment, Mr. Harvey, on the rationale of that settlement, if there isn't a significant connection? Why would the chemical companies be willing to settle out of court for that amount?

Mr. HARVEY. I certainly can. They basically wanted to buy their way out of an awful lot of legal fees and a lot of continuing bad press that was going to go on for a long time, plus the down-side risk of a jury verdict that was against them.

That was truly the settlement of a legal dispute. A judgment was made on a business basis by a lot of chemical companies, that they were going to get off a lot easier by simply putting out what turned out to be, in the aggregate, a very substantial amount of money and then leaving the problem behind. I might add that both the trial judge and Court of Appeals in reviewing the settlement commented that the plaintiffs in the case failed to present credible evidence of causation.

Senator MURKOWSKI. Wouldn't a settlement of a class action suit by one group still leave open the possibility that another group might initiate a class action suit on the same basis? In other words, you are not necessarily closing the door by accepting the settlement of $180 million with just one group. Potentially, there is another group which might try to do the same thing.

Mr. HARVEY. I would assume so, but I have no idea what the terms of the settlement were.

Senator MURKOWSKI. I don't either, any more than we do on the $180 million settlement.

We will have an opportunity to hear further on that particular issue. But I see a problem because I would assume that if one group could bind together, file a suit and get a $180 million settlement, why wouldn't another group logically do it?

And yet, that is really the job of the VA: to be an advocate in the interest of veterans with respect to Agent Orange and its complications, which have already been enunciated at great length today.

Mr. HARVEY. I would assume that one aspect of the case that was settled is that there is a presumption that the majority of potential claimants have already signed onto the original class that participated in that.

Senator MURKOWSKI. You are implying that there is some finality?

Mr. HARVEY. I would think that that may be so.

Senator MURKOWSKI. I think that would be interesting to have available to the Committee, whether or not that door still remains open. My next question follows that. Some time after that class action suit was settled, there was a study of Kansas farmers exposed to herbicides containing 2,4-D and 2,4,5-T for some 20 days per year. And they found a substantial incidence of non-Hodgkins lymphoma relative to nonfarm types. Farmers with a more frequent exposure had an eight-fold increase.

Assuming that information is generally correct, we then have the study of Marines in Vietnam's so-called "I Corps" in comparison to the Army and other Marines. That study found that there were many more Marines with non-Hodgkins lymphomas, for reasons that I guess are still under study.

Doesn't that seem to develop a case for the realization that those exposed are more likely to come down with complications?

Mr. HARVEY. I don't believe it does, Senator.

Senator MURKOWSKI. Why doesn't it?

Mr. HARVEY. It is my understanding that the herbicides used in Kansas that were administered by these people were used over an extended period of time—15 or 20 years by these people—on a continual basis; and those herbicides did not contain dioxin, the contaminant that has been all along blamed as the source of the problem for Vietnam veterans.

Again, as I said earlier, I do believe that all of these things indicate that there is a scientific issue which needs to be pursued and needs to be pursued on a scientific basis. I would hope that it would not be pursued on a political basis.

Senator MURKOWSKI. I would hope so, too. You know, we seem to be left with the dilemma that we are never going to be totally sure, one way or another. Science is not going to be able to come to a conclusion. Should we spend more money for studies to try to get a greater degree of conclusiveness? Or should we spend that money instead to compensate veterans who are affected by non-Hodgkin's lymphoma and who were in an area where they may have been exposed to Agent Orange?

I have been on this committee since I came to the Senate, and this issue has consistently been before us. I know your presentation, citing your own credentials and your own dedication to addressing the problem, is one by which I am certainly moved. I am absolutely convinced of your sincerity.

But I am also somewhat frustrated with the process. We are trying to reach a conclusion, and we try to achieve that through recommendations from scientific knowledge. And your comments and point of view are your responsibility in representing the VA.

But here we are, almost where we started, still looking at studies that don't tell us what we feel that we have to have to make a decision on what to do. We will probably never reach a conclusion on what we should be doing in addressing compensation in this area.

Mr. HARVEY. I think you need to consider doing the studies, Senator. If you were not to do that, I don't know how you could then bound this issue by a single disease in this case and in the case of S. 1692, your legislation. I think that the studies have done a lot.

You know, we have had several studies on birth defects, all of those have indicated that there is no higher incidence of birth defects among children whose fathers were exposed to dioxin or who served in Vietnam.

Other studies have eliminated different things. There still is a tremendous range of different problems that the veterans themselves ascribe to Agent Orange; not scientifically, but they themselves feel in their minds that Agent Orange could possibly be the causative effect of a problem that they are suffering from.

I don't know how you draw the line.

Senator MURKOWSKI. But by the same token, we may be left with the reality that the scientific community may never be able to answer the question conclusively.

Mr. HARVEY. And there are people here today who will be testifying, including the VA Advisory Committee on Environmental Hazards, who are far better competent to talk about the specifics of that than I.

Senator MURKOWSKI. If they reach that conclusion, does it affect your evaluation that we should continue the process indefinitely? Or is there some time or some point where we are going to simply have to say: We have examined the record, and we have initiated the studies; we have had the best scientific evidence; and now we are faced with the reality of having to make a decision? Is that the premise you see as inevitable, recognizing that some even today may say you can never reach a final conclusion?

Mr. HARVEY. That could be a problem, but I certainly would not want to abbreviate the process. I think that there are a lot of studies now ongoing—financed by us, by CDC, and others—who have concerns about this issue.

And I sure would like to get the results of those before I saw any congressional enactment of legislation to compensate other particular diseases.

Senator MURKOWSKI. I commend you again for your commitment and dedication. Thank you.

Mr. HARVEY. Thank you.

Chairman CRANSTON. Thank you. There is a statement by Senator Mitchell for the record. Now, we will go to Senator Daschle.

[The prepared statement of Senator Mitchell appears on p. 133.]

Senator DASCHLE. Mr. Chairman, I would just like to ask if I could put in the record the sort of studies that indicate that birth defects and suppression of the immune system are related to exposure to Agent Orange. Mr. Harvey said there is absolutely no evidence. So, if we could submit that for the record, I would appreciate it.

Chairman CRANSTON. I think we should not include long studies in the record because of their size.

Senator DASCHLE. Maybe we could include the bibliographies, though.

Chairman CRANSTON. All right.

[The bibliographies appear on p. 149.]

OPENING STATEMENT OF SENATOR DeCONCINI

Senator DECONCINI. Mr. Chairman, thank you, and I thank you for your continued leadership in conducting these hearings to try to get a clear picture here of the herbicide exposure and the problems relating to Agent Orange.

Your leadership has been demonstrated once again, as well as that of the ranking member, to try to resolve if we can, or at least get a better feeling of this whole problem. I am pleased at the interest level these hearings have generated. It was not so long ago that Agent Orange was not a familiar term to many Americans, and that has certainly changed.

As you know, I have always supported the many efforts of this committee to fully investigate the impact of the use of this deadly herbicide in Vietnam, and I reiterate that these efforts must continue. I have continued interest in pursuing the problem and the medical effects that are associated with it.

Mr. Chairman, I regret that I have to go to the Judiciary Committee for its markup shortly, and I will not be here to listen to the entire hearing. But I appreciate the effort that this committee is making. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you very much. Senator Rockefeller?

OPENING STATEMENT OF SENATOR ROCKEFELLER

Senator ROCKEFELLER. Thank you, Mr. Chairman. This is a dilemma for me; in fact, it is a somewhat painful one. I remember, as do we all, when our Vietnam veterans returned from the war.

They were not always given the honor that they deserved. But then, I also recall the days when the honor that they deserved began to come.

West Virginia is not a big State, but it is a very patriotic State. Our State's casualties in the Vietnam war were greater in proportion than any other State. That is a sad fact; and as the Governor for 8 years during the time consciousness was emerging about Vietnam veterans, I tried to do things to help.

In fact, in 1982, Mr. Chairman, I started an Agent Orange program which was a new idea at that time. It was set up as an assistance program, and it still exists today. It is recognized as one of the best programs focused on Agent Orange in the country.

We are lucky to have a fellow by the name of Chuck Conroy who directs this program. Chuck Conroy is a nationally recognized expert on this issue. He sits on advisory committees to major research efforts that are going on, which have been referred to today.

What we tried to do in West Virginia with our Agent Orange program was to reach out to veterans of that war who had not been reached out to, at least by governmental bodies, to try to get them in touch with VA hospitals and other helpful services. We had a number of centers around the State where people could come and talk.

I am puzzled about this particular debate on Agent Orange compensation. I am puzzled about the issue, as I say, and I agonize over it.

I remember very well, Mr. Chairman, that there was a time back in the late 1960s when the Vietnam war was going on that there was vociferous argument about black lung and whether or not there should be a presumption granted to miners to qualify them for black lung compensation. I felt there should be. The Congress felt there should be the presumption of black lung disease for miners who had been in the mines for more than a decade.

Basically, we said that if you had been in the coal mines for a certain number of years—in this case, I think we said 10 years—that there would be the presumption that one had black lung. It was almost impossible to imagine being in a mine—if anybody on this committee or in the audience has ever been in a mine for more than 20 minutes, you come out convinced that something is going to happen to you. After 10 years, you pretty well know your health has been damaged.

Well, in the early Reagan years, the presumption granted had been taken away by Congress. It does not exist any longer, and I agonize over that, as I do over this issue.

I recall the hearings we had on atomic veterans. There are only 100 or so atomic veterans in West Virginia. I think we concluded at that time that we didn't have total scientific proof of the connection between radiation exposure and certain illnesses, but there certainly was a lot of evidence—clear evidence.

We knew who they were—atomic veterans; they were marked literally. Their records were clear; and yet, we took 40 years to decide what to do about helping them.

And then, we finally did something about it this year and passed presumption-based compensation legislation.

So, I am agonizing about the question of Agent Orange compensation. Having said that, I have to know more, too. I also feel a fiduciary responsibility to taxpayers. We have a powerful responsibility to those who represent the country in war. So, I am listening, Mr. Chairman; I am listening, and I am agonizing.

This is not an easy process; I recognize that. I know that our people went over there. I know that they were exposed. I know that they came back, and they didn't get credit from their country. Now, they are not getting credit from the medical community. And I am agonizing over the process.

I don't like it. I think it ought to be resolved. There has to be a clinical way of resolving these things so that Senator Daschle, who has worked so long and hard on this—he has talked about birth defects; that has been written about, from my point of view, with some clarity. I am not a doctor, but there seems to me to be some clarity on that.

It is as if we have to wait for the entire answer on everything before we do anything. We often do things in Congress that way, and often end up therefore doing nothing.

Can we take paces? Can we establish certain kinds of precedence? I listen and I agonize, Mr. Chairman. I thank you for your indulgence.

[The prepared statement of Senator Rockefeller appears on p. 135.]

Chairman CRANSTON. Jay, I thank you for that very helpful statement. This is an agonizing procedure, and it is a very, very difficult one considering all the different facts that are presented to us and many of the uncertainties that are before us.

I want to thank Tom Harvey, who has been our witness for the VA. We appreciate it.

Mr. HARVEY. Thank you, Mr. Chairman. I want to thank everyone on the committee for making me welcome today.

Chairman CRANSTON. Thank you. We will now go to Dr. James Mason, Director of the Center for Environmental Health and Injury Control, Centers for Disease Control, U.S. Department of Health and Human Services, also representing the National Institute of Occupational Safety and Health, accompanied by Dr. Vernon N. Houk; and Major General Alexander M. Sloan, Deputy Surgeon General, U.S. Air Force.

Dr. Mason, if you would please begin by summarizing your testimony? Then, we will hear from General Sloan, and please remember the 5-minute rule. We have taken a long time with the first witnesses. We must now move as expeditiously as we can.

STATEMENT OF DR. JAMES O. MASON, DIRECTOR, CENTERS FOR DISEASE CONTROL, U.S. PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALSO REPRESENTING THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, ACCOMPANIED BY DR. VERNON N. HOUK, DIRECTOR, CENTER FOR ENVIRONMENTAL HEALTH AND INJURY CONTROL

Dr. MASON. Mr. Chairman and members of the committee, Dr. Houk and I are delighted to be here today. It is going to be a very tough job to summarize this in 5 minutes, but I will do my best.

I first would like to just say a word about the status of the Agent Orange Exposure Study. We have included some details of it in the written testimony, but I would like to have Dr. Houk hold up a chart. To do an Agent Orange Exposure Study, you have to identify individuals who served in Vietnam and who were exposed. We worked with the U.S. Army and Joint Services Environmental Support Group to find several approaches to identifying exposed veterans.

We also used veterans' own assessment of exposure. Then to validate whether the Army records, the military records, and the veterans' assessment of exposure were valid, so that we could carry out an Agent Orange Exposure Study; we tested over 600 of these veterans, those who were most likely to have been exposed to Agent Orange.

The chart shows that, of the Vietnam veterans, we found two of over 600 who had levels that were above what would be expected in people who were similar in age and other experience—other than service in Vietnam.

This was the basis for our saying we couldn't do an Agent Orange Exposure Study because to do a study we have to compare people who were exposed to those who were not exposed. Now, it would be possible to carry out such a study; but if our ratio is approximately 1 or 2 per 600, to get a cohort of about 2,500, we would have to screen at least 1.6 million Vietnam veterans.

Since this group was the most likely to have been exposed, we are not sure that even by screening 1.6 million veterans we would have been able to identify a cohort large enough to study them.

What would be the cost of screening 1.6 million veterans? Somewhere in the range of $1 billion just for the screening determinations to identify the cohort; then you would have to carry out the study from that point.

Therefore, when this was presented to the Agent Orange Working Group and the Office of Technology Assessment, they concurred with us and said that pursuing an Agent Orange exposure study of combat veterans was not practical.

On the other hand, working with the Air Force on their study, it is obvious—this data in red—shows that by looking at those individuals that were actually mixing and dispensing Agent Orange, it is very easy to identify people with elevated levels.

So, I just show this. You will be hearing from Major Sloan on their study, and I don't intend to get into that. I would say that for those who actually handled Agent Orange, there is no question that we can identify individuals that have dioxin in their blood today, in 1987 or 1988. But, we had difficulty in identifying such individuals among combat troops and, therefore, it was agreed by all those that reviewed the situation that we should not waste the taxpayers' money by plunging ahead and comparing a group that we couldn't really show was exposed with a control group.

Enough on the Agent Orange Exposure Study, what I really want to spend time on is the status of the Vietnam Experience Study. I am not going to talk about the mortality component of that study, which has already been reported to you and published. The rest of my time will be spent discussing the morbidity findings because that is new data.

Attachment B in my written testimony is a summary table of the significant findings from the morbidity component of the Vietnam Experience Study. Hundreds of observations were made, and these are the only significant findings from this component.

In the telephone interview, nearly 18,000 randomly selected veterans were traced with 94 percent of the Vietnam and 92 percent of the non-Vietnam men located during 1985 and 1986. Of the men located, 93 percent of the Vietnam and 91 percent of the non-Vietnam veterans were interviewed, which is a tribute to their extraordinary spirit of cooperation and willingness to participate.

Interviews revealed a broad similarity between the two groups in terms of current demographic and social characteristics, such as education, income, employment rates, and marital status.

Although the two groups were similar socioeconomically, the Vietnam veterans reported more current limitations in activities, more current use of prescription drugs, and a greater prevalence of many types of diseases, and somatic and psychosomatic symptoms.

However, as will be discussed in a moment, most of these self-reported findings were not verified during the examination process. Although the study is not large enough to evaluate risk of specific types of cancers, the two groups were similar in the total reported number of physician-diagnosed cancers.

We are conducting the selected cancer study to evaluate risk for certain cancers which have been identified in the scientific literature as possibly associated with industrial or occupational exposure to herbicides.

The Vietnam veterans reported more problems with impaired fertility, yet both groups reported fathering the same average number of children. The Vietnam veterans also reported more birth defects; however, these reports were not verified by information contained in birth records.

On the medical and psychological examination; for the examination component we had invited a random sample—approximately 42 percent—of the interviewed men for a comprehensive physical, psychological, and laboratory determinations. The results showed few current differences between the two groups, despite the many differences elicited by telephone interview.

For example, there were many large differences in reported skin problems; but on examination, all skin conditions, including scars from possible past chloracne, were found with similar frequency in the two groups.

Psychological evaluation of the men who were examined was done through standardized interviews and questionnaires. Although most men in both groups fell within normal limits in these evaluations, certain conditions were more prevalent among Vietnam than non-Vietnam veterans. These conditions included current psychological problems, primarily alcohol abuse or dependence, anxiety and depression.

Of significance here is that, although alcohol abuse or dependence was higher in the Vietnam veteran group, illicit drug abuse or dependance at the time of examination was not different between the two groups; about ½ of 1 percent of each group fell into this latter category.

Analysis of combat related post-traumatic-stress disorder showed about 15 percent of Vietnam veterans reported ever experiencing symptoms which met diagnostic criteria of this disorder. These symptoms diminished over time, but 2.2 percent had still experienced an episode of post-traumatic-stress disorder during the month before examination, up to 20 years after their service in Vietnam.

With regard to reproductive outcomes, we found no differences, as I said earlier.

With regard to specific medical conditions addressed in pending legislation, on lung cancer we found one unconfirmed case in the Vietnam group and three cases—two of which have been confirmed—in the non-Vietnam group.

Six cases of non-Hodgkin's lymphoma—three confirmed—have been reported in the Vietnam group and one case confirmed in the non-Vietnam group.

This concludes my testimony. I will be happy to answer any questions that you might have. We would like to submit also the detailed analysis of our study for the record, if that might be possible.

Chairman CRANSTON. Thank you very much. Counsel has some questions.

[The prepared statement of Dr. Mason and the analysis appear on p. 202.]

Mr. STEINBERG. I know you were trying to conclude your opening statement rapidly when you gave us the statistics on lung cancer and non-Hodgkin's lymphoma. Do you wish to say anything about your study's findings on those figures?

Dr. MASON. I think we would simply say that we don't have all the cases confirmed; and therefore I think it is really too early to say whether the data is statistically significant. With regard to the non-Hodgkin's lymphoma, the jury is still out. Reported here this morning have been several suggestive studies, but I don't think at this point we have evidence that non-Hodgkin's lymphoma is associated with exposure to Agent Orange.

I think we are going to have to see the outcome of the Selected Cancer Study before we will have statistical evidence as to whether there is an association.

Chairman CRANSTON. Thank you very much. General Sloan, are you going to make a brief statement?

General SLOAN. Yes, sir.

STATEMENT OF MAJ. GEN. ALEXANDER M. SLOAN, DEPUTY SURGEON GENERAL, U.S. AIR FORCE

General SLOAN. Thank you, Mr. Chairman and members of the committee. I have with me Dr. Wolf, who is the Senior Principal Investigator in the Ranch Hand Study, and I appreciate the opportunity to have him sit at the table.

I will try to make up some of your time. I thank you for the opportunity to present an update on the progress of the Air Force Health Study of personnel exposed to herbicides in Southeast Asia.

Our study, based on a scientific approach, includes those who sprayed herbicides—the Ranch Hand group—and a group of matched comparisons. It is a planned 20-year research effort.

Our protocol was extensively reviewed by multiple scientific peer groups. The study includes detailed questionnaires and periodic clinical examinations by internal medicine, neurology, and dermatology specialists, as well as psychological and extensive laboratory testing.

Participation in the study has been excellent. To date, we have published four mortality reports and two morbidity reports, the most recent in October of 1987. At this time, there is insufficient evidence to support a cause-and-effect relationship between herbicide exposure and adverse health in the Ranch Hand group.

The study has revealed a number of medical findings that require continued surveillance. In full context, the results of this study are encouraging evidence that at this time the current state of health of the Ranch Hand group appears to be unrelated to herbicide exposure in Southeast Asia.

However, we still cannot exonerate the herbicides.

Recently, a new method of determining dioxin exposure has been developed. The blood serum assay will provide an accurate measure of the current body burden of dioxin. This greatly improves our ability to calculate individual exposure levels.

As you heard, a pilot study of 200 serum samples confirms clear and meaningful dioxin exposure did occur in the Ranch Hand group.

You have asked for my comment on two bills currently under consideration, S. 1787 and S. 1692. The Air Force objects to the presumption of causality in cases of lung cancer, non-Hodgkin's lymphoma, and certain immunosuppressant disabilities as a result of exposure to Agent Orange in Vietnam veterans.

Both bills disregard the research effort under way to evaluate the health effects of herbicide. Early data from the Air Force Health Study does not support the presumptions made in these legislative items.

I have addressed the findings of several other studies in my witness statement, which has been submitted for the record.

The Science Panel of the Agent Orange Working Group has concluded that the two studies which are most likely to answer the questions of possible health effects of phenoxy herbicides are the Ranch Hand Study and the National Institute of Occupational Safety and Health Study of Occupationally Exposed Workers.

In conclusion, the Air Force Health Study is the premiere federally funded herbicide related study under way. Its findings are important to our veterans and to their families. With your continued support, our work will continue. I will be happy to answer any questions you may have.

Chairman **Cranston**. Thank you very much. We appreciate your opening statement.

[The prepared statement of General Sloan appears on p. 222.]

Chairman **Cranston**. Dr. Mason, before we discuss your statement which is before us, I want to discuss a general AIDS issue briefly. First, I congratulate you on this excellent pamphlet that the CDC has just produced on AIDS to be mailed to every U.S.

household. I think that is a very fine piece of work and very constructive.

Dr. MASON. Thank you.

Chairman CRANSTON. It separates fact from fiction, and it is straightforward and understandable. It should be very helpful in educating the American people on the facts about AIDS. I am sure you would agree, however, that educating gay and bisexual men and others at risk for AIDS and motivating them to adopt risk-reduction behavior warrants a more specialized and targeted approach.

That is why I wanted to make sure you had seen the letter I sent you last Thursday.

Dr. MASON. I have seen it.

Chairman CRANSTON. You have seen that? Good. It covers the Senate debate on action regarding a similar amendment when S. 1220 was on the floor 2 weeks ago. That debate and the Senate action make clear what the conferees attempted to do in their statement accompanying the conference report on the fiscal year 1988 continuing resolution; but the Senate does not intend to restrict education materials targeted to gay and bisexual men or IV drug abusers.

I am glad you have seen the letter. I hope you will be able to act favorably on my recommendation that the CDC adopt new, positive guidelines for the awarding of fiscal year 1988 AIDS education grants reflecting what has clearly been shown to be the Senate's intent.

I trust that is what you will be able to do?

Dr. MASON. We are looking at that right now, Senator Cranston.

Chairman CRANSTON. When can you give me a response on that question?

Dr. MASON. Our response is being prepared, and I hope within a few days it will be back in your hands.

Chairman CRANSTON. Fine, thank you. Dr. Mason, I have a series of questions for you; and I would be glad to have you or Dr. Houk reply, as you wish, to them.

In the Vietnam Experience Study, statistically-significant differences were found with respect to four areas: one, past hepatitis B infection; two, low sperm concentration; three, stool occult blood; and four, high frequency hearing loss. Will you or Dr. Houk comment on the significance of each of those findings.

Dr. HOUK. The finding of past infection of Hepatitis B is not to be unexpected because, in the area of the world where those people served, it is a very prevalent disease.

Hearing loss is known to occur around combat and the noise of combat.

The occult blood in the stool is a finding in about 1½ percent more of the Vietnam veteran group than the non-Vietnam veterans. We don't know what could be the cause of that; there is no known cause. We have ruled out infections with a lot of intestinal parasites and those sorts of things.

With regard to the decreased sperm counts, Senator, the findings are unexplained. We don't know why the Vietnam veterans have a decreased number of sperm and some abnormalities in morphology. It has made no difference, however, in their being able to father children; both groups are about the same. It does not appear to result in birth defects.

I think the finding that has shown to be of significance is the 2.2 percent of the Vietnam veterans who still have combat-related post traumatic stress disorder.

If I could clarify how that diagnosis was made, we used a very complicated system designed and approved in the same manner as that of the American Association of Psychiatrists.

Chairman **Cranston**. I thank you for that response. Dr. Houk, according to the scientific literature, what are the consequences of a low semen count or a reduced proportion of morphologically-normal sperm cells? Specifically, has either an increase in birth defects or inability to conceive been associated with either a low semen count or a reduced proportion of morphologically-normal sperm cells?

And, were such associations found in Vietnam veterans in the study?

Dr. **Houk**. Male infertility is usually associated with counts below 5 million. Everybody agrees on that. We are talking around 20 million, as opposed to a normal sperm count of around 50 to 100 million. There is no good data on that.

There is no evidence, either in the literature or in human data, that the abnormality of the sperm is related to structural birth defects in children. The pertinent data is the ability to father children; and as you will note in the more detailed analysis, the Vietnam veterans say that it took them longer to father children.

Chairman **Cranston**. Did they have the same number of children, though?

Dr. **Houk**. Yes, 1.6 on average.

Chairman **Cranston**. Dr. Mason, statistically-significant differences between Vietnam and non-Vietnam veterans also were found with respect to psychological health and prevalence of PTSD. Would you or Dr. Houk comment on the significance of those findings?

Dr. **Houk**. I think that they are increased, but they are not greatly increased. The difference is about 2 percent—2 percent of the non-Vietnam veterans group compared to about 4 percent in the Vietnam veterans group for depression and anxiety, and higher proportions of alcohol abuse in the Vietnam veterans group.

I think these veterans, as a group, Senator, are functioning in society and are doing very well. They have the same socioeconomic background—basically, they make the same amount of money and have the same satisfaction with their quality of life—as the other groups on all these particular issues.

Chairman **Cranston**. What about the significance of the PTSD findings?

Dr. **Houk**. The PTSD findings, to me, are the most significant findings of the study. This study is a random sample of Army veterans who served during the Vietnam era. That is about 2.1 million Army veterans during this period of time; 2.2 percent of 2 million people is not an inconsequential number.

These people were having medically diagnosed post-traumatic-stress disorder. It has caused some interference with their lives, 16 to 20 years after service in Vietnam. I would think that ought to be recognized—and it is being recognized—and the appropriate health benefits should be given to veterans.

Chairman CRANSTON. In the blood validation part of the Agent Orange Study, although almost all of the veterans tested had dioxin levels which did not exceed background levels of exposure, two veterans have substantially higher levels. Do you have any hypothesis for those two levels; and how likely is it that they are representative of a larger number of Vietnam veterans?

Dr. HOUK. The veteran with the highest level was 45. That veteran denies any exposure in Vietnam or before Vietnam or after Vietnam; and no exposure to household dioxin sources of which he is aware. The one with the 25 level reported going through sprayed areas for about 180 days while he was in Vietnam.

But there are 300 other people in that group who went through areas sprayed in Vietnam for similar numbers of days who had no abnormal dioxin blood levels. We do not know why.

As Dr. Mason said, this does not say that people in Vietnam were not exposed to Agent Orange. We think that in those individuals who were occupationally involved—that is sprayed or handled Agent Orange, principally the Air Force Ranch Hand group and Chemical Corps workers, and people like that—we can identify higher levels several years after leaving Vietnam.

Chairman CRANSTON. How do you reconcile the overall lack of exposure found in that study with the reports of veterans that they did receive substantial exposure?

Dr. HOUK. Twenty-five percent of the veterans who had normal values said that they had been exposed in Vietnam. There was a great deal of spraying of a lot of things in Vietnam. Unless they knew what they were being sprayed with, they would be confused, themselves.

Several of the people in this study also described having their clothes soaked in the materials with which they were sprayed; and yet their values are low.

Chairman CRANSTON. Dr. Houk, would you please comment on the statistical significance of the numbers Dr. Mason provided from the VES study on lung cancer and NHL?

Dr. HOUK. In regard to lung cancer, there is no evidence in the literature except for the VA Proportionate Mortality Study and the study out of Nitro, W. Va. The author of the Nitro, W. Va. study cautioned that it cannot be used because again there is no smoking data.

So far we have seen in this group of randomly selected Vietnam era veterans three cases of lung cancer; one in the Vietnam group, two in the non-Vietnam group.

The soft tissue sarcoma and non-Hodgkin's lymphoma issue is a much more difficult issue to look at. The study we are doing on selective cancers is especially designed for that. These are all the cancers that have occurred in a 4-year period in eight cancer registries in the United States.

Chairman CRANSTON. Actually, I am asking you about the statistical significance of the data in your study, the VES Study.

Dr. HOUK. On the cancers? What I was saying is that, with only six cancers, this could be a throw of the dice. In other words, with regard to lung cancer, there were more case in non-Vietnam veterans than there were in Vietnam veterans. On the non-Hodgkin's lymphoma, there were more cases in the Vietnam veterans than the non-Vietnam veterans.

But the numbers at this point are the kind that you can get with random numbers; and that is why you need to follow this up. The numbers show that it is something that needs to be looked at.

Chairman **CRANSTON**. But are you saying you can't derive any conclusions, that there is no significance from those statistics?

Dr. **HOUK**. That is right. There is no scientific significance in those findings at this point; and we won't get that kind of significance out of the Vietnam Experience Study. It will have to come from the special cancers or Ranch Hands studies or, as General Sloan referred to, the National Institute for Occupational Safety and Health Study of Occupational Exposure.

That is where we are going to have to get that data, in order to get enough numbers to have some significance in our findings.

Chairman **CRANSTON**. I have some more questions, but I have used 10 minutes. So, I will go to Senator Rockefeller.

Senator **ROCKEFELLER**. Thank you, Mr. Chairman. I have looked at these statistics, Dr. Mason and Dr. Houk; and it seems that where you indicate that there are not significant differences, that you emphasize that quite carefully.

And then, where there do seem to be significant differences, for example with the reported birth defects—-which Senator Daschle referred to, and I did also—you underplay them.

Particularly in regard to birth defects, you emphasized quite strongly when there isn't a difference. When there is a difference, you seem to say that perhaps that was "underreported." And I have seen that phenomenon before because there is a tendency of people, when they are trying to reach an overall conclusion, to be uncomfortable with things which may subtract from the consistency of that overall conclusion.

I listened as you indicated that these numbers are based on telephone interviews. My own experience with telephone interviews is that they often are not anything like personal interviews at all. To use a cross analogy, if you are doing political polling these days and you want a good poll, you go spend 45 minutes in the person's house; you don't use the telephone.

And in fact, you spend the first 20 minutes of that conversation asking all kinds of questions in a very serious manner about which are irrelevant to your purpose, with the goal of establishing a relationship showing that you are not a hostile person, that you are not intruding in a person's life, and that in fact it is all right to talk; and the individual relaxes.

I guess what I am asking is: Have any of these people been talked to in person? Have you folks talked to them in person? The telephone is a wonderful thing, but we are talking about some serious statistics here.

I know you want to answer me, but when you talk about alcohol abuse and you say it is 13.7 for Vietnam and 9.2 for non-Vietnam, that strikes me as a very large difference. Anxiety, depression, and I think the previous witness indicated that there are differences there, but those are very large differences.

Those are called 100 percent differences—twice as much. You know, the average person would look at that and say: Well, 4.5, 2.3, 4.9, 3.2; you can say that that is not a big difference, but maybe it is. And maybe the telephone becomes something which distorts some of this. I would like your reaction to what I am saying.

Dr. MASON. I tend to agree with what you have said. The telephone interviews were handled on two large cohorts—9,000 in each, Vietnam veterans, and veterans who did not serve in Vietnam.

Then, approximately 2,500—a smaller group that we could handle and we could afford—were randomly selected and their way was paid to Albuquerque, N.M. to the Loveless Clinic. That 2,500, inclusive of each cohort, then spent a number of days—not a 45-minute personal interview—but a number of days at the Loveless Clinic, where they were examined medically from the top of their heads to the bottoms of their feet, blood was drawn, and almost every conceivable appropriate laboratory examination was done.

Then, they were subjected to a very, very careful psychological examination, as objective as one could make. These tests were carried out by people who didn't know which cohort these 2,500 belonged to, whether they were Vietnam veterans or non-Vietnam veterans.

That is why you do find interview differences that are significant; significant differences from those things reported over the telephone. When you get down and really start measuring objectively or spending more time on it, many of these interview differences—for example, when people said they had a child with a birth defect and you examine all of the 2,500 and look at the birth certificates of their children—then those differences began to disappear, exactly as you were talking about.

That is why there are interview differences. I am not saying that people are hyping it or dishonest or anything else; it is just that one group may differentially remember things.

For example, the non-Vietnam veterans did not remember birth defects that actually had occurred and that were found when they looked at the birth certificates. So, you get differential remembering and things of that nature. That is why you really have to go to a basic examination where you have a 1 on 1 evaluation to finally look at those things that can be examined.

Senator ROCKEFELLER. In those areas where Agent Orange was sprayed, surely there must have been Vietnamese people who were there at the time?

Is there any knowledge at all with respect to what has happened to those people?

Dr. HOUK. What has happened with respect to the Vietnamese people? No. The one hospital for birth defects, in what was then Saigon, is a hospital that treats nothing but that. So, people go to that hospital with every child who has a birth defect.

But there is no good data about what happened to the Vietnamese people.

Senator ROCKEFELLER. Has a request been made for that? It seems to me if we are trying to find out cause and effect relationships, that that certainly would be the trail to track?

Dr. HOUK. When I was chairman of the Agent Orange Science Panel in 1982, we considered that with a great deal of concern and had some experts within Vietnam working with WHO, et cetera, on their records. After looking at this issue intently, we concluded that the record systems were such that it would not be useful to try to explore that approach any further.

Senator ROCKEFELLER. Not be useful?

Dr. HOUK. We could not do it.

Senator ROCKEFELLER. I understand that we could not do it. We could request or ask that it be done, could we not? I mean, if we are trying to look for cause/effect relationships, that would strike me as about as direct a one as we could find.

Dr. HOUK. I do not know that the exposure of the Vietnam people and their perception of exposure would be any different than the perception of exposure of the U.S. veteran because we know that many of the veterans went through the same areas several days after they were sprayed.

Dr. MASON. Senator Rockefeller?

Senator ROCKEFELLER. Senator Daschle was there, and I wasn't. I don't know the pattern, but it would seem to me that the pattern was that we would spray, then our soldiers would come in. In the case of the Vietnamese, they perhaps were not forewarned so they were there during the spraying; therefore, isn't there something fairly interesting to be learned from that?

Dr. MASON. The problem is exposure. You have to have a group that you are fairly confident were exposed, and then you have to look at birth defects in that group compared with a group that wasn't exposed.

If you don't tie it down, there are a lot of other things that might be going on in Vietnam aside from Agent Orange that caused birth defects. Unless you can narrow it down to the only difference in the two populations being exposure and nonexposure, then you are not sure that the differences you find are related to Agent Orange.

Senator ROCKEFELLER. What could be going on in Vietnam—a land that I understand does not have a great deal of chemical and industrial activity—what could be going on other than Agent Orange that would be different?

Dr. MASON. You just don't know. For example, there are drugs for malaria that if taken during time of conception could cause problems. There are a whole series of things that may have an effect on the occurrence of congenital defects, even use of tobacco, use of alcohol, and malnutrition.

You really have to narrow it down to what you are studying. You could, in retrospect now, I guess, go back; and if you could identify a cohort of exposed persons in a large enough group with validated blood levels of dioxin on board then you could compare that group with a nonexposed group. Then you would have to make sure that they were equivalent in malnutrition, and the use of tobacco and alcohol, and malaria therapy, and all of these other things, so that you were controlling for those differences.

Then you might be able to look at that, but it would be a very difficult study.

Senator ROCKEFELLER. Final question, Mr. Chairman. With respect to reported birth defects, there sure is a difference there;

and yet the word "underreporting" is used in terms of the non-Vietnam group. Why are there pains taken here to say there is "underreporting"?

Dr. HOUK. In asking people if they have had children with birth defects—these are ascertained by the fathers and not the mothers—typically, a father underreports. We asked that question several years ago.

From the experience that we have, what we found in the non-Vietnam veteran population is about a third underreporting, which is what we find in other studies we do. With Vietnam veteran fathers, the reporting was not quite 100 percent, but closer to 100 percent.

We took a sample of these men, we saw them face to face at Loveland and asked them about all their children. We then got their permission to seek all the hospital records about the birth of that baby and all that baby's records, and whether it was normal or abnormal or whatever.

The rate of birth defects was 60.9 per 1,000 in the children of Vietnam veteran fathers and about the same rate in the non-Vietnam veteran. This is the standard rate of birth defects, based upon the large surveillance system that we have.

We believe that the difference in reporting here is that the non-Vietnam veteran father reported fewer birth defects had occurred than the Vietnam veteran father. One feeling is that the Vietnam father may have remembered more about this than the non-Vietnam father.

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you. Before continuing with this panel, we have to make a slight change because a witness has to leave very shortly. You can stay at the table, but I would like to ask Admiral Zumwalt to come forward.

As we all know, Admiral Zumwalt is the former Chief of Naval Operations and former Commander of Naval Forces in Vietnam. I am delighted to see you again and look forward to your testimony, and I appreciate your presence.

STATEMENT OF ADM. ELMO R. ZUMWALT, JR., FORMER CHIEF OF NAVAL OPERATIONS AND FORMER COMMANDER, U.S. NAVAL FORCES, VIETNAM

Admiral ZUMWALT. Thank you, Mr. Chairman and members of the committee. I am pleased to be here. With regard to the Government witnesses I have listened to this morning, I have found what I would describe as an awful lot of bad rhetoric and bad analysis.

The situation, I think, is far from what has been described here. Let me just cite a few of the examples. I won't talk about the fact that the fine Tony Principi and Tom Harvey are not "walking time bombs," and they certainly are not. When I came back from World War II, I was not a "walking time bomb;" and when I came back from Korea, I was not a "walking time bomb;" and when I came back from Vietnam, I was not a "walking time bomb."

But those are not the subject; the subject are those who are "walking time bombs." I would point out, for example, that the Ranch Hand Study is not particularly significant because: "we would expect to find cancer in less than one of the small number involved there, and" those who sprayed were less exposed than those who were sprayed on the ground in the sprayed danger areas.

In regard to the Kansas City Study——

Chairman **Cranston**. Sir, would you explain why that would be?

Admiral **Zumwalt**. Yes, sir. The people in these planes were protected from the spray by protective clothing and took showers when they got back and were in places where the food was sheltered. Those in the field took no showers for weeks at a time, had no sheltered food, and just drank the water.

With regard to the Kansas City study, which has been discussed, Dr. Mason made the statement that that involved 2,4-D whereas the Vietnam people were sprayed with Agent Orange. But 2,4-D is one of the principal substances in Agent Orange; and, therefore, the fact that 6 to 8 times as many Kansas farmers exposed to that substance came down with lymphoma is relative to the Vietnam situation.

With regard to dioxin levels in the Agent Orange Exposure Study, there is much to be questioned about that. The Army logistics personnel—and we have heard about that large logistics tail—was certainly there and their lesser exposure reduced the overall percentage who have experienced problems. On the other hand, in those areas where the logistics people are not included in the data—and this is not made clear in the testimony about the Marine Corps study—where the logistics tail was the Navy—there were not any Navy personnel in the study. There was a much higher record of cancer in the Marine data; and so this omission of the Navy logistics tail is critical to the result.

Dr. Arnold Schecter has taken samples of dioxin in the South Vietnamese and compared them to samples taken from the North Vietnamese, where we did not spray; and there is a marked difference.

With regard to the Marine Corps study, I think it is extremely important to recognize those numbers. If you take the logistics personnel of the Navy, you had 110 percent more lymphomas and 58 percent more lung cancers.

With regard to the Vietnam Experience Study, which has been somewhat denigrated here, I read those numbers and I say that, in comparing the Vietnam veterans to the non-Vietnam veterans, there were 80 percent more who suffered low sperm, 29 percent more who had fertility problems, 135 percent more who had psychological problems, 49 percent more who had alcohol problems, 45 percent more who had skin disorders, and 31 percent more who had children with birth defects.

And I say that those are significant numbers. We have established now in Kansas farmers what one of the two substances in Agent Orange does. We know from our own studies in this country what the 2,4,5-T that was sprayed for 6 years in the national forests in Oregon can do. We found that women had three times as many birth defects and other problems.

I simply do not understand why this Government is unable to get at the truth and not learn more from what is available. I believe, Mr. Chairman, that it is absolutely reasonable to conclude that there is causal relationship between Agent Orange and cancer and birth defects and that it is irresponsible not to make a service-connection here, in regard to the birth defects and lung cancer and the more important and prevalent lymphomas.

I would want to conclude by saying that as I read the bills, I do not believe my oldest son who has lymphoma would qualify; and I do not, therefore, think that this testimony is designed in any way to help him, who does not need financial support. But I believe that the veterans who are suffering from the effects need to be addressed and that the data should not be selectively reported to this committee.

Chairman CRANSTON. Thank you very much for your testimony. I have some questions, but I will submit them in writing if you have time problems. I will go to Senator Graham if he has any questions.

Senator GRAHAM. No questions, Mr. Chairman.

[The prepared statement of Admiral Zumwalt appears on p. 238.]

Chairman CRANSTON. Senator Daschle?

Senator DASCHLE. Thank you, Mr. Chairman. I want to commend Admiral Zumwalt for his excellent statement. There is no hype there; there is no rhetorical flourish. You did the committee a real service, and I commend you for providing that information.

In the short time that I know the committee has, with the chairman's permission I would like to ask Dr. Albanese, who wrote the Air Force interim report, to come to the table to answer a couple of questions.

Chairman CRANSTON. Could we do that a little bit later?

Senator DASCHLE. Sure. All right.

Chairman CRANSTON. Admiral Zumwalt, I thank you very much.

Admiral ZUMWALT. Thank you.

Chairman CRANSTON. Senator Kerry wanted to testify, and I believe he is here. So, I would like to ask him to come in at this point. Dr. Houk, I have one question for you while we are waiting for Senator Kerry. Would you like to comment on the percentages that Admiral Zumwalt gave us from the VES study?

Dr. HOUK. You calculate it in a different way. We were showing the differences between the two groups. One group had 5 percent and another group had 7 percent, and we didn't know if that was statistically significant or not.

Depending upon which side of the question you want to go on, Senator, you could use the number of Vietnam veterans and say the non-Vietnam veteran had 20 percent less and the Vietnam veteran had 30 percent more, et cetera.

The base data are in the study, and all the base data available will be provided as soon as the document leaves the printers.

Chairman CRANSTON. We will give you a copy of the transcript so you can respond in writing, if you would, to the statements made by Admiral Zumwalt.

While we are waiting for Senator Kerry, who will be here in a moment, I will proceed. Since the VES study does not focus on the effects of Agent Orange, what significance do its results have with respect to the Agent Orange issue?

Dr. HOUK. I don't believe the results relate specifically to Agent Orange exposure. This study was designed so it was service in Vietnam and all that entailed was studied. We had hoped to answer you about Agent Orange by the Agent Orange Exposure Study, and we found that was not possible to do from the military records.

Chairman CRANSTON. I was very disappointed, as I am sure we all were, that the CDC's Agent Orange Study had to be cancelled. In your written statement, you acknowledge that there has been criticism of the methods used to select the veterans who were seen as likely to have had significant Agent Orange exposure.

Have the researchers working on the New Jersey project, or anyone else for that matter, made specific suggestions to CDC regarding better ways to classify individuals with respect to exposure, that might allow the Agent Orange Study to go forward?

Dr. MASON. The best way to classify them is with regard to whether they were actually involved in spraying and handling Agent Orange. That is the best way to find exposed people with elevated dioxin levels.

Beyond that, we looked at every possible way, using military records or the assessment made by the veterans themselves.

Chairman CRANSTON. Have suggestions been made of other ways to go?

Dr. HOUK. Yes. We have taken all of the suggestions into account. The major criticism is based upon the method of selection. We looked at the veteran being in the area, and going through sprayed areas—in all the areas that were involved to our knowledge; and we found no differences except in those who were occupationally exposed by spraying.

Chairman CRANSTON. Would you furnish the committee with a summary of the proposals that have been made to you and your evaluation of them?

Dr. MASON. Yes, sir.

Chairman CRANSTON. Dr. Mason, what diseases fit within the category of immunosuppressant disabilities, a term used in S. 1787?

Dr. MASON. What diseases would fit into that?

Chairman CRANSTON. Yes.

Dr. MASON. A number of diseases that are characterized by lack of ability to ward off—primarily—infection. For example, AIDS is an acquired immunodeficiency syndrome caused by a virus that specifically attacks T-helper lymphocytes.

One could postulate, I guess—those who believe that dioxin is able to do something to the immune system—that somehow there is a selective destruction of the immune system, which would leave them susceptible to the same opportunistic infections that might occur with acquired HIV immunodeficiency.

There are also other manifestations that might occur. It is a whole series of events that would occur because a person had a deficient immune system.

Chairman CRANSTON. Thank you very much. We will now go to Senator Kerry for his statement. Senator Kerry?

STATEMENT OF HON. JOHN F. KERRY, A U.S. SENATOR FROM THE STATE OF MASSACHUSETTS

Senator KERRY. Thank you very much, Mr. Chairman. I am delighted to be here, and I thank you again for holding another hearing on another important veterans' issue. Also, I am delighted to appear here with Admiral Zumwalt, who I knew personally from my Vietnam service. He personally pinned a medal on me, and I am grateful to him particularly for his continued involvement and concern with this issue.

Mr. Chairman, I would like to ask at the outset that a statement of support for this legislation from Governor Dukakis be admitted into the record today.

Chairman CRANSTON. It will be in the record.

[Senator Kerry furnished the following information:]

A. Response of Governor Michael S. Dukakis to the Vietnam Veterans of America.

AGENT ORANGE

Despite the now overwhelming evidence that Agent Orange exposure may well be linked to various cancers, including non-Hodgkins Lymphoma and lung cancer, the VA steadfastly refuses to treat Agent Orange related problems as service-connected disabilities for purposes of compensation. VVA supports current legislation (S 1787 and HR 3486) mandating disability compensation for Agent Orange victims suffering from non-Hodgkins lymphoma, lung cancer, and diseases associated with immuno-suppression.

Do you support the above mentioned legislation granting disability compensation for Vietnam Veterans exposed to Agent Orange?

Yes. Massachusetts leads the nation in state funded Agent Orange scientific and medical research on the effects of exposure to Agent Orange.

B. Quote from The Stars and Stripes, March 7, 1988:

"Governor Dukakis cited his funding of Agent Orange research in Massachusetts".

Senator KERRY. Thank you. Mr. Chairman, last year when I testified before this committee on Agent Orange, I stressed the importance of this issue to Vietnam veterans. It was important then; I think it is more important today.

Agent Orange is literally a question of life and death to a lot of veterans. The issue is not going to go away, and I think it is time for the Congress to address what is fundamentally an issue of decency, if you will, and no matter what the state of scientific evidence that exists today.

Obviously, Vietnam is one of our most controversial wars in history; and you spoke out courageously against it in the early years. Others in this room totally supported it to the end. That is not the issue today; and I think we should avoid anything that suggests that Agent Orange and the efforts of us all are somehow linked to any guilt or any sense that Vietnam veterans are owed more than veterans of other wars in other eras. That is not what is at issue here.

There is no need to refight any of the old battles. This is a question of not making Vietnam veterans the last victims, in a way, of the war in which they fought. I just don't believe that the debt, however, to anyone who served should be repaid simply in rhetoric or in symbols.

I support the legislation to have a Cabinet level veterans' representative; but I can't help but feel that somehow that falls prey to a sense of fulfillment of obligation that is somewhat symbolic because veterans have enormous support in this country without that representation and obviously all the other things: the flag waving at the parades, the parades themselves, the resolutions that have been passed.

Those are working, and they are important. But what is really substantive is addressing the concern of the Vietnam veteran who knows in his heart and soul and gut, who has read countless studies, that the skin rashes that they once had in Vietnam after washing with the water or eating food didn't suddenly appear out of nowhere.

And when they make associations with what happens to farmers and other people from exposure to dioxins, 1 and 1 do make 2; and 2 and 2 do make 4. And they have been living with that progressive process for a long time, Mr. Chairman, with a sense in their soul and in their heart, as well as their mind, of the connection between their service and the particular ailment.

Now, I am not going to tell you as a rational person that the scientific evidence is complete on every aspect of every disease or that we can say there is a causal connection with finality on each and every complaint a veteran makes with respect to possible exposure. I am not going to make that; I don't know any veteran who will make that claim. That is not what this issue is really about.

This issue is about a presumption. It is about a relationship, a relationship between one institution of our Government and the people who served that Government. And the question is: Are we going to leave that relationship in adversarial form for 20 years or 40 years—as we did with atomic veterans who stood up in front of the blasts of radiation and were 40 years later told there is no relationship between your cancer and that radiation, until finally we moved in the Senate within this past session?

It is a relationship, Mr. Chairman. That is what we are talking about, and the question is whether there is enough evidence, by virtue of all the studies that have been done, to say that that relationship is such today that we as a Congress ought to respond to these demands.

We know that it takes sometimes 20 years for a cancer to develop. We have agreed that as to chloracne there is a connection. Now, all that this legislation seems to do is extend the presumption to two other diseases, about which there is significant statistical data, and to continue to study the linkage between other diseases.

That is not costly. It doesn't need a lot of money. It doesn't mean that everybody who has a claim is going to get it. It means we are addressing the issue of the relationship between a Vietnam veteran and the institutions which were set up to try to meet his or her needs for having served their country.

Now, Mr. Chairman, could I ask for a little additional time?

Chairman **CRANSTON**. A little bit.

Senator **KERRY**. Thank you. In 1983, Mr. Chairman, the VA Agent Orange Registry found excessive cancers among Vietnam veterans, non-Hodgkins lymphomas, and cancers of the oral cavity, the pharynx. A 1983 study by the Massachusetts Agent Orange Commission found excessive numbers of soft tissue sarcomas and cancer of the kidney among Vietnam veterans exposed to Agent Orange.

In 1984, a Ranch Hand baseline study found a higher level of skin cancers, systemic cancers, twice as many cancers of the lip, oral cavity, and pharynx. A 1985 study in Wisconsin found excessive incidences of soft tissue sarcomas in Vietnam veterans who had been exposed to Agent Orange.

A 1986 study in West Virginia found higher incidences of non-Hodgkins lymphomas and cancers of the testes, larynx, and respiratory systems among Vietnam veterans. The preliminary results of the CDC Vietnam Experience Study released in 1987 showed excessive instances of lymphosarcomas, leukemia, brain cancer among Vietnam veterans.

The VA Mortality Study released in 1987, a survey of 50,000 veterans, showed rates of death due to non-Hodgkins lymphoma, 110 percent higher than normal; deaths due to lung cancer, 58 percent higher than normal among Marines who served in areas heavily sprayed with Agent Orange.

A 1987 Ranch Hand followup study showed excessive incidences of skin cancers, systemic neoplasms, lymphomas, soft tissue sarcomas, three times as many cancers of the oral cavity and pharynx, twice as many cancers with bronchus and lung, and three times the number of testicular neoplasms.

The recent report released by the Ranch Hand Study in March of 1988, at the request of Senator Daschle and myself, showed higher incidences of tumors, birth defects, psychological disorders, and blood toxicity.

And then there are the results just released this week from the CDC, the Vietnam Experience Study.

Mr. Chairman, I will just close by saying that I understand that none of this is 100 percent conclusive, but this legislation doesn't assert 100 conclusiveness. It asserts a transition in the relationship, as I said, with only a presumption.

I think the time has come for us to respond to the compelling evidence about dioxin and cancer and the relationship between toxicity and the problem that we have. I just think personally that that would be a most significant step that would be taken and has been taken since the Vietnam veterans came back to respond to their real needs, not symbolic, but real needs.

I thank the chair for its indulgence.

Chairman CRANSTON. Thank you very much, John, for a very strong statement. I know you feel very strongly about this. I just have a couple of questions, but I will ask you to respond in writing.

[The prepared statement of Senator Kerry appears on p. 245.]

Senator KERRY. Excuse me, Mr. Chairman. Has Chris Gregory been introduced?

Chairman CRANSTON. He is coming in at the end.

Senator KERRY. If I could just introduce him now? Chris Gregory is a Vietnam veteran who is deeply involved with the Massachusetts Agent Orange Study. He has dedicated a significant portion of his life in recent years to pursuing this issue. He is very knowledgeable about it. He is currently working in Massachusetts.

I am just delighted that he is going to testify, and I thank the Chair for allowing him to be here. Thank you very much.

Chairman CRANSTON. We welcome him, and we will hear from him later on, toward the end of our session.

I would like to mention that the OTA, at page 8 of its testimony, suggests that the CDC should examine now the data from the Selected Cancer Study pertaining to the non-Hodgkin's lymphoma.

Since we have two bills pending now on service-connected issues, that study will be very helpful. Would there be any problems entailed in doing that?

Dr. Mason. The reason for the length of time required before a report on the Selected Cancer Study can be made is that we have to accumulate a significant number of the selected cancers in order to make that report. There is the lag time waiting for these cancers to occur and then for them to be reported to the cancer registries throughout the Nation.

After they have been reported to the cancer registries, then they have to be ascertained and confirmed by histological diagnosis. So, we are simply waiting for enough cancers to be reported and confirmed histologically.

We have concerns that we won't have the data. We understand the impatience and how useful it would be to have that data right now, but we can't invalidate the scientific approach and the peer review of that kind of study. We would be happy to go back and look at what we might be able to do to speed up the process, but we certainly wouldn't want to, in any way, undermine the scientific validity of the study in doing that. But might we just say that we would like to examine the possibility? And we well understand why having that kind of data would be appropriate.

I would like to just comment, too—not in any way being antagonistic to Senator Kerry—but with regard to the statistics that he gave from CDC, do not let my silence be understood to be concurrence. I was not familiar with some of the data that he gave that indicated that CDC had shown an association with some diseases, and I think that is true for the Air Force as well.

General Sloan. Yes, sir.

Chairman Cranston. Dr. Mason or Dr. Houk, does this blood dioxin analysis reveal anything other than the amount of dioxin exposure? That is, can it determine the date of exposure of the kind of dioxin compound to which there was exposure, or distinguish between civilian and military exposure?

Dr. Houk. It cannot determine the date except by half-life analysis backwards. You can determine the kind of dioxin. The dioxin that we measured, 2378 TCDD, was the dioxin that is present in the Agent Orange contamination.

The veterans that we examined, although not all of them because each analysis costs $1,000, had the whole battery of the 40 or 50 dioxins that can be measured. The only increase was in the 2378 TCDD, which is the same result that we found in Ranch Hand personnel and the same that we found in production workers handling 2378 TCDD in this country.

Chairman Cranston. Could you distinguish between the civilians and the military?

Dr. Houk. No, if the exposure was 2378 TCDD. The dioxin that was mentioned in Kansas is different—and that can be identified in 2378 TCDD.

Chairman Cranston. While you have determined that it is not possible to conduct a study of all Vietnam veterans, it has been suggested that there are small identificable groups of veterans, such as those who were part of the Chemical Corps, who likely have substantial exposure. Do you believe that a study of those individuals could be useful and should be conducted?

Dr. HOUK. If we could find a group, Senator Cranston, that was sufficient and comparable in all other things, both exposed and not exposed. One of the reasons specific groups were not included in the overall Agent Orange Exposure Study was to keep everything as comparable as possible, except exposure.

Chairman CRANSTON. Is any effort being made to do that?

Dr. HOUK. We have offered help to the Veterans' Administration in establishing dioxin analysis in the laboratories if they choose. I think there are some veterans who were occupationally exposed who are undoubtedly going to have high dioxin exposure blood levels.

If I could quickly add, we have the Air Force Health Effects Study and the NIOSH study, which show very high levels of dioxin. The analysis of the health effects from those two studies, which are going to be completed in the next couple of years, may give some answers of yes or no.

Chairman CRANSTON. You say that such a study would be duplicative and wouldn't add to the Ranch Hand Study?

Dr. HOUK. I don't think so, sir.

Chairman CRANSTON. I would like to turn briefly to General Sloan, and then I know that Tom Daschle has some questions.

Dr. Mason and Dr. Houk, did you have another commitment?

Dr. MASON. Yes, Mr. Chairman.

Chairman CRANSTON. You may be excused. We thank you very much for your testimony and participation.

Dr. MASON. Thank you very much, Mr. Chairman.

Chairman CRANSTON. General Sloan, I would like to insert in the record at this point a report prepared by Dr. Albanese on the data from the 1984 Ranch Hand report, along with three letters that I received from Dr. Albanese, and two of the primary Ranch Hand Study researchers Dr. Michalek and Dr. Wolfe, regarding their role with respect to the study, and also the reports from the OTA and the Veterans' Advisory Committee on Environmental Hazards.

So, that will all be in the record.

[The reports and letters appear on pp. 577 and 689–705.]

Chairman CRANSTON. I have some questions on the February 1988 report by Dr. Albanese. Is that an official Air Force report?

General SLOAN. Yes, sir. It was a technical report released by the School of Aerospace Medicine. It went through all the channels for an independent scientist releasing a report. So, it is an official Air Force report. It is not, however, part of the Ranch Hand officially released report that went through the peer review process.

Chairman CRANSTON. Is it a collaborative product, or is it essentially the work of Dr. Albanese?

General SLOAN. I would say that it was a work that involved efforts from Dr. Wolfe, Dr. Albanese, and Dr. McGaelic at various stages of the project. At the final conclusion of the study, I would say that it contains the work of Dr. Albanese.

Dr. Wolfe and Dr. McGaelic chose to withdraw from the formal process that would have made them—on technical review.

Chairman CRANSTON. Did it pass peer review?

General SLOAN. It did not pass the peer review in the sense that I described in my opening statement of the oversight groups that are involved in the Ranch Hand Study. It passed peer review at the School of Aerospace Medicine, inasmuch as the commander signed it out and said that it was adequate for publication.

Chairman CRANSTON. Was it submitted to go through?

General SLOAN. Yes, sir. Not in its final form, I don't believe, but in a very substantive form it was submitted earlier and was criticized. And it was an attempt on the part of Drs. Wolfe and Michalek to resolve those criticisms that they were participants in that effort of technical review and found themselves unable to do so to everybody's satisfaction, to reach a consensus.

Chairman CRANSTON. What was your role in the preparation for release of it?

General SLOAN. I was not involved in the preparation for release of that.

Chairman CRANSTON. Dr. Albanese concluded in his report that there five clinical areas in which differences in the direction expected according to the dioxin literature exist between the Ranch Handers and their controls. Do you agree with Dr. Albanese, and if so, what significance do you believe these differences have with respect to establishing a causal association between dioxin and those health outcomes?

General SLOAN. I am not an investigator, and I must say that my credentials are not as illustrious in the evaluation of scientific research, either in a peer review group or of any investigators of this area of medicine.

My review of that report is—and Dr. Albanese can obviously speak for himself—that the major thrust of that was to review the literature and look at animal data and try and correlate that with any potential trends or statistical significance that had appeared in the 1984 data; and basically, that is what this report addresses.

We have heard testimony previously today on the value of the animal data; and of course, the animal data as it relates to humans is problematic in many cases, and herbicide or dioxin is no exception to that.

Chairman CRANSTON. Dr. Wolfe, do you have any comment on the proposal——

Dr. WOLFE. As far as the proposal goes at this time, I personally see no basis from our work or other work that has been discussed this morning that would lead me to making any causal associations.

There are obviously differences, and we analyzed thousands and thousands of statistical events. Differences do occur and are seen, but we then have to look at that for consistency and patterns.

And at this time, at least in our study, I see no basis to make any causal associations.

Chairman CRANSTON. Thank you. General Sloan, do you have any brief—and I stress the word "brief"—further comments on the Albanese report?

General SLOAN. I guess I would say—and Dr. Albanese and I have discussed this—I would disagree with some of the tone and the comments of the peer review process as it existed previously;

and I would agree that their comments are valid and would, therefore, take that position.

Chairman CRANSTON. Thank you. Tom, do you have questions?

Senator DASCHLE. Thank you, Senator. There is going to be a vote at 11:30, so I know that we will probably have to recess in a moment. Dr. Wolfe, do you disassociate yourself from the so-called Albanese report?

Dr. WOLFE. No, I don't. The report is technically correct.

Senator DASCHLE. The report is technically correct?

Dr. WOLFE. Technically correct. I would have written it differently.

Senator DASCHLE. You submitted it, did you not, with Dr. Michalek to the peer review committee?

Dr. WOLFE. We were initial authors on an earlier draft.

Senator DASCHLE. All three of you?

Dr. WOLFE. Right.

Senator DASCHLE. Is there anything in substance that is different from the original submission to the peer review committee?

Dr. WOLFE. In substance, I believe it is pretty similar.

Senator DASCHLE. Pretty much the same?

Dr. WOLFE. Yes, pretty much the same. It was a matter of size and tone.

Senator DASCHLE. So, you really are not disputing the scientific fact or the substantive information. You are disputing, as you say, the style and tone?

Dr. WOLFE. The style and tone. I think the substantive information is consistent with our previous report, that we had not identified causal association.

Senator DASCHLE. I would like to ask Dr. Albanese and Dr. Michalek to come up to the table at this time, if I could, Mr. Chairman, in what limited time I have. I know they are in the audience and they have been the subject of a lot of discussion in the hearing this morning.

Chairman CRANSTON. Fine.

Senator DASCHLE. I have just one question for you, Dr. Michalek. It has been said that there is really no difference whatsoever between this report and the 1984 report. Do you share that view?

Dr. MICHALEK. In its conclusions, that is right; but there is an additional analysis in this report that is important. That corrects a statement made in the baseline report regarding the birth defect analysis on reported birth defect data.

That is one of the major features of this report.

Senator DASCHLE. How does that differ?

Dr. MICHALEK. The baseline report incorrectly concluded that the observed difference was due to minor reported birth defects in Ranch Hand children. In this technical report, the analysis shows—as I pointed out—that the observed difference does not change with severity.

In other words, the conclusion in the baseline report on reported birth defects was incorrect, and that is one of the major messages or pieces of information in this report.

Senator DASCHLE. I am not a scientist. Would you tell me whether you would characterize that as a fairly insignificant thing or a fairly significant departure?

Dr. **Michalek**. I would say, first of all, that, as we have already seen in the other studies, this kind of data is subject to being over and underreported. We have no way to assess that without record verification of all the children, which is now under way.

Senator **Daschle**. You say then the distinction between the 1984 report and the 1988 report in that regard is significant?

Dr. **Michalek**. It is a piece of information we have been wanting to get out, and I am glad it is out.

Senator **Daschle**. Dr. Albanese, why did you write the report?

Dr. **Albanese**. Fundamentally, because I wanted to understand more about dioxins. In modern statistical testing, of every 20 statistical tests, one will show a big difference just by chance. So, if you are looking at 100 or 200 tests, you could have 5 or 10 differences just by chance.

But suppose dioxin only caused five or ten effects? You could lose it in statistical noise; that has been a concern of mine.

Senator **Daschle**. Do you think that has happened?

Dr. **Albanese**. I wanted to be sure it hadn't happened.

Senator **Daschle**. But has it happened in terms of the overall discussion of the issue?

Dr. **Albanese**. I believe people have not adequately and sufficiently used fundamental understanding of what dioxin does as a molecule, to target their interpretation of the data. Yes, sir.

I came down to 11 critical end points; and of those 11, 6 had expressions that were suggestive of dioxin effect. The incomplete expression of dioxin effect is such that I cannot implicate dioxin; but the fact is that in 6 of 11 points, there is dioxin expression. That tells me I cannot exonerate it.

Furthermore, given the imprecisions in our state of the art, nonetheless an imprecise index, exoneration at this time would be hazardous.

Senator **Daschle**. If you could just summarize—as the chairman indicated—in as succinct a way as possible, what the report says.

Dr. **Albanese**. The punch line is one cannot implicate dioxin as a causative effect in the Ranch Hand group, nor can one exonerate dioxin of having caused adverse health in the Ranch Hands.

Senator **Daschle**. Do you share the concern expressed by Dr. Michalek about birth defects?

Dr. **Albanese**. Yes, indeed. One of the subgoals for us was to show the corrected analysis.

Senator **Daschle**. General Sloan, if that is the punch line, does the Air Force have a different position?

General **Sloan**. I thought, sir, I had made that clear in my opening statement.

Senator **Daschle**. But you said that this was expressly the views of one individual, and I was unclear if that is the case, that the Air Force was disassociating itself with the conclusions of the report.

General **Sloan**. I did not mean to say that it was the expressed views of one individual. I thought I said that it was a collaborative effort up until the end, where there were differences in style, substance, tone, and as a matter of fact——

Senator **Daschle**. What is the difference in substance, in your opinion?

General **Sloan**. I may have overstated that particular word. It depends on what you define as substance. I personally think the chart that is reflected in Dr. Albanese's report that shows pluses and minuses is a substantive chart that will lead the reader to believe that there is an adverse health effect there.

That is consistent with that found in the animal literature. If I were doing that, I think that is substantive——

Senator **Daschle**. But this wasn't just animal literature, was it, Dr. Albanese?

General **Sloan**. No, I was talking about the relationship between the animal data and possible human health effects.

Senator **Daschle**. But he did study in this case both animals and humans, did he not?

General **Sloan**. He reviewed animal literature and studied no animals.

Senator **Daschle**. Is that correct, Dr. Albanese?

Dr. **Albanese**. No, I did a toxicological review of animal and human data and formally set up a profile to target the examination of the data.

Senator **Daschle**. And you collaborated in that study with your two colleagues?

Dr. **Albanese**. Yes, sir. I did.

Dr. **Wolfe**. Not in the review.

Dr. **Albanese**. No, no. I did the review and submitted my draft to Colonel Wolfe and Dr. Michalek.

Senator **Daschle**. But that was all submitted to the peer group, was it not?

Dr. **Albanese**. Yes, it was.

Senator **Daschle**. So, again, there was no difference in substance?

Dr. **Albanese**. No, sir.

General **Sloan**. I am going to take a little issue with that. You asked me—and I may have overstated it—if I thought there was a substantive difference between 1988 and 1983 and previous and current Ranch Hand reports. I will stick by my personal opinion, and I would say that, yes, I think there is now.

I would agree that there is absolutely no difference in the data. There is no difference in the numbers, in the statistical handling of those numbers, or whatever; but I think there are substantive differences in the reports. And I would offer that as my opinion.

Senator **Daschle**. Colonel, you are quoted in Newsday as saying the only difference between the 1988 report and the 1984 report "is a result of scientific debate and wordsmithing for the public." That is the quote.

Is that actually your opinion, that the only difference between the two reports is a mere wordsmithing?

Dr. **Wolfe**. Scientists have always had trouble translating our internal technicalities of our work, translating that in a way that the public—lay persons of all sorts—can understand it; and that is always a very difficult problem. And the differences of opinion among ourselves have been largely tone and style, the way we phrase things and the way we write things.

Senator **Daschle**. But I have to differ, and I do it with all deference. Dr. Michalek just said that there was a significant difference with regard to the ramifications of the new information on birth defects. Now, that seems to me to be more than wordsmithing.

And you say that is just a question of style?

Dr. WOLFE. We are dealing with reported birth defects.

Senator DASCHLE. Dr. Albanese, could you comment on that?

Dr. WOLFE. May I finish, sir?

Senator DASCHLE. Oh, please.

Dr. WOLFE. We are dealing with reported birth defects. Now, as that issue evolves, in 1984 we realized that reported birth defects were subject to differential reporting and we have begun a full evaluation and verification of those reports on an excess of 6,000 children born to the men in our study.

In the context of that effort and the value and importance of that verifying work, I view the technicalities of this correction, if you will—using other's words—as not being of tremendous importance.

Senator DASCHLE. I am going to finish with this question because I would like both Dr. Albanese and Dr. Michalek to respond to that, and then I am going to have to go vote. Would you do that, please?

Dr. ALBANESE. Let me see if I can get back to the question because I think I have lost it in the responses.

Senator DASCHLE. Dr. Wolfe is quoted as saying it is just a matter of wordsmithing, that there really isn't any significance in the differences that exists between the 1988 and the 1984 studies. I would like to ask if that is true in light of what Dr. Michalek has just indicated to the committee.

Dr. ALBANESE. In writing the report, I tried to sharpen my personal focus with regard to dioxin. I think I said explicitly that dioxin cannot be implicated nor exonerated. In other words, you know it is not just positive and negative.

Those are not the only two options when you conduct a study. There is a third option—inconclusive. That is to say, we could report no causation nor deny causation. And I am trying to assert that, at the moment, our study is inconclusive.

I made that statement rather explicitly. I believe that statement is implicit in both the 1984 and the 1987 reports.

General SLOAN. It was explicit in the 1984 report. We had never stated that the Air Force can exonerate dioxin from any adverse health effects.

Senator DASCHLE. Would you state after 1988 that this is reassuring to veterans and their families?

General SLOAN. I guess.

Senator DASCHLE. That is not very reassuring.

General SLOAN. You are asking me for a personal opinion; and I will say yes, it is reassuring. When I talk to somebody like Jack Spey—and you can ask him the question this afternoon, or whenever he testifies—in my across the table discussion with him, I, in my own capacity as a physician, am reassured by the fact that there is no apparent difference in many things that we thought were very possibly going to jump right out and hit us betwixt the eyes.

Now, an example would be systemic cancers. You have heard much about systemic cancer here this morning. I would say that

that is still a murky area. The idea that there are differences in our two groups in systemic cancers is not a valid one.

There is a group interaction that says enlisted flyers have a higher, statistically significant rate of systemic cancers than enlisted ground troops. That doesn't make much sense to us because we think that enlisted ground troops were more heavily exposed.

And as a matter of fact, the preliminary dioxin serum assays that we have would go to substantiate that.

So, I am very reluctant to make that clinical association and that great leap, which you would say there is reasonable doubt; and I would disagree with you. That is all.

Chairman CRANSTON. May I interrupt? I will have to leave shortly, and Jon Steinberg, our counsel, will ask some questions that I wanted to pose to you. And then, he will call the next panel; and I will get back, and then the next panel can make their opening statements.

Senator DASCHLE. Thank you. I am going to have to conclude, too. Dr. Michalek, do you have any final comment?

Dr. MICHALEK. I would just like to add that I am glad this record is being made today.

Senator DASCHLE. Thank you.

Mr. STEINBERG. General Sloan, we have a few questions for you, if we may? Has an excess of systemic cancers been found among the Ranch Handers?

General SLOAN. Not in the unadjusted data. That is, if you take all Ranch Handers and all comparisons, there is no difference. There is, however, a desirability in dealing with the increase of power and being able to detect a difference, if you look at things by different categories in those groups; and that was done in this case.

And as I mentioned, the enlisted flyers have a statistically significant higher incidence rate of systemic cancers than their enlisted comparisons. The numbers are very small. They are so small that 1 to 2 cases of cancer amongst these people would cause a difference in that statistical significance.

It is also important—as Dr. Michalek has mentioned—to be able to relate that to exposure index. We now are able to do that better by the availability of the blood test; but I would like to talk just a bit about the exposure index, if that might be permissible, sir?

Mr. STEINBERG. May I just follow this with another question we had? Do you attach statistical significance to the excess that you referred to with respect to the enlisted personnel or not?

General SLOAN. Sir, that is a mathematical determination; and yes, the P value is .034, I believe, that is statistically significant. So, yes, I would attach statistical significance to it. I think what we have heard about statistical significance and that to which Dr. Albanese referred is that, if you have 20 observations, one of them is going to be statistically significant wrongly.

And of course, in a study like ours where we had 2,000 or 3,000 end points, you may statistically significant results that may be the result of chance in a couple of hundred cases.

So, the strength of this business is in trying multiple things together that point in the same direction; and in this case, it points in exactly the opposite direction because the enlisted flyers were not the most heavily exposed.

Mr. **Steinberg**. Let me ask if any of the other gentlemen would care to comment on the systemic cancer question.

Dr. **Michalek**. I would like to clarify that a little bit. The excesses we saw in the enlisted flyers—the Ranch Hand enlisted flyers and their controls—we saw five verified systemic cancers in about 300 enlisted flyers on the Ranch Hand side and none in the comparison side on an equal number of people.

I am not enthused about a finding like that—especially one which did not regress on exposure and one which is contradictory to our current understanding of the exposure of these people.

Mr. **Steinberg**. Can you explain what you mean by "regress on exposure"?

Dr. **Michalek**. A classical herbicide effect would be revealed by not only a group difference but by regression on exposure. That is, people with heavier exposure should have more of the disease than people with low exposure.

Mr. **Steinberg**. So, that is regression.

Dr. **Michalek**. And we have not found that in any end point.

Of course, we have doubts about the exposure index. Now, if in addition to finding a difference in cancer in a subgroup, we also found a regression on current body burden, we will have discovered the strongest possible epidemiologic evidence of an effect.

Mr. **Steinberg**. General, would you like to comment on this?

General **Sloan**. I would, sir. To start back at the beginning of the Ranch Hand Study, one of the major strengths of the study, as you have heard this morning, it is difficult to get to who was and who wasn't exposed.

One of the major strengths of the Ranch Hand group was that it was assumed they were exposed, notwithstanding some people's opinion to the contrary that they took frequent baths and that sort of thing. I think we had scientific evidence that says they were exposed.

When you get down to the very precise scientific aspect of it, to do the regression analysis that you would like to be able to do—that Dr. Michalek referred to—you need to have individual exposures. We were only able to come up with a good estimate of group exposures. That is not very good for the kinds of numbers that we are dealing with, and specifically when we get down to five cases of cancer.

If we had many thousands of people in the study, that would be a different story; we don't. So, I would say that, from my standpoint, the exposure index that was developed at the time was the most satisfactory, state of the art, and clearly identified properly as we had assumed all along, people who were in fact exposed.

We probably aren't very good in saying whether this individual or that individual was more or less exposed by group. There is a little bit of overlap there. Now, we are able to do that in a more refined sense.

That doesn't mean, however, that we can't tell what exposure was or that this business has been seriously flawed from the outset, as some people would contend. I personally don't feel that. I don't think there is anybody at this table who feels that the Ranch Hand Study is seriously flawed.

Mr. STEINBERG. Let's find out. Dr. Albanese, do you believe that the Ranch Hand study is seriously flawed?

Dr. ALBANESE. The word "flaw" in epidemiology indicates unfixable, or irremediable defect or deficiency. I do not believe our exposure index is irremediable. I would say this, though and I would like this to be very clear as you consider all the studies: these group-based exposure indices are poor, and that lowers the probability that it can detect a dioxin effect if one exists; and I would like to say one other thing personally.

I am very excited about the opportunity of having a dioxin measurement in the blood; but please remember, the exposure of humans to dioxin was not an exposure directly into the blood. It was cutaneous, respiratory or alimentary—skin, breath, eating. A lot of care must be taken in our use and interpretation of serum dioxin. It is our best bet, I believe, until something further comes around, perhaps like a tissue marker.

It is our best bet, but we must use it with care because the exposure was not direct to the blood.

Mr. STEINBERG. Dr. Michalek or Dr. Wolfe, do you want to comment on the question of the extent of the efficiency of the exposure index——

Dr. WOLFE. I think the exposure index that we initially calculated was state of the art. It was the best possible way to approach our group of study participants. In many environmental and industrial occupational studies, that is still the way that exposure indices are calculated.

Fortunately, the advent of the serum assay gives us the tool that will refine our estimates of exposure and really make our study much more valuable.

Mr. STEINBERG. So, your conclusion is that the study is not lacking in value.

Dr. WOLFE. Oh, absolutely. That is correct.

Mr. STEINBERG. Dr. Michalek, do you have a brief comment?

Dr. MICHALEK. It is most likely that the estimate of exposure will be substantially improved with the application of this assay. There is some evidence that some of the Ranch Handers may not have been heavily exposed at all. Others, of course, were very heavily exposed, as you can see from the pilot study.

That introduces a misclassification of Ranch Hands, which attenuates our ability to discover differences in disease rates. Once we correct that with application of the assay, the study will become much more powerful than it currently is. And we will have the ability for the first time to ask questions about the direct relationship between dioxin and current health.

Mr. STEINBERG. General Sloan, you were just talking about the serum analysis. Do you intend to proceed with the serum analysis of all of the samples which you currently have on all of the Ranch Hands?

General SLOAN. Yes, sir.

Mr. STEINBERG. And how will you fund that?

General SLOAN. I can't answer that at this time.

Mr. STEINBERG. If supplementary funding is not provided to you, will you still be able to proceed to complete that?

General **Sloan**. I am unclear as to the exact funding situation. It is my understanding that the Office of Technology Assessments is currently assessing the scientific merit of our proposal.

Mr. **Steinberg**. I believe that the OTA has already responded and said that you should proceed with the proposal that you gave them; and it is acceptable to OTA that you should proceed with it.

General **Sloan**. Sir, I have not seen that. If that be the case, then it is my hope that we can proceed with the tests.

Mr. **Steinberg**. There is a letter from OTA saying you should proceed with that. Will there be no difficulty if that is the case?

General **Sloan**. It is my understanding that there are funds available to do that, given that decision.

Mr. **Steinberg**. Would you check out that situation and report back to the committee on that?

General **Sloan**. I certainly will, sir.

Mr. **Steinberg**. Could you summarize very briefly those adverse health effects which you have found that you believe have statistical significance?

Dr. **Wolfe**. That takes a little reconstruction and some thought. We have found an increase in reported self-assessment of health, where the Ranch Hand group recorded fair to poor self-perception of their health.

We have a mixture of health effects. We have the reported birth defects, which we are currently reevaluating. We looked at liver function and found that the Ranch Hand group, of 11 liver function tests, has an elevation in one test of liver function, and the comparison group has a significant elevation in another one.

That is difficult to interpret. Again, you would look for patterns across all liver function tests. If we had a pattern that showed consistency in many of these; and in the other tests, there were no significant differences.

On the psychological testing, we found that there were, on one psychological test, the Ranch Handers' scores on the side suggesting a perception of their health that was poorer than in the comparisons. On another psychological test, the comparison group had a more adverse score than the Ranch Handers did.

Some of the abnormalities in psychological testing that we had seen in 1984 were no longer present. Depression was no longer a significant problem; anxiety was no longer a problem.

When we looked at the cardiovascular system, in 1984 we found a pulse difference. We measured those pulses with a doppler test and restricted smoking and found that the pulses were not different.

We looked at cardiovascular disease, as far as heart attacks. We looked at high blood pressure. And those two conditions were not different in the two groups. When we lumped all other forms of heart disease, we did find a significant group difference. Within that categorization, we combined about 10 or 15 different kinds of heart disease in one group, including congenital heart defects, including pericarditis, which is an inflammation of the sac lining that encloses the heart.

We looked at many of these heart conditions and found there was a significant difference overall, and then we looked at this large lumped category; but in looking at that data, there was no single diagnosis that jumped out, as showing much in the way of a difference between the two groups.

Mr. **Steinberg**. And that difference was higher among the Ranch Hands?

Dr. **Wolfe**. Higher among the Ranch Hands. Cardiograms were identical in the two groups. There are two conditions that we always worry about the most: high blood pressure and heart attacks; and those were not different in the two groups.

There were some other differences in some individual laboratory tests; but again, we looked for consistency and patterns, and we found none.

Mr. **Steinberg**. General Sloan?

General **Sloan**. Yes, sir. Likewise, in the comparison group, there were certain areas where there were more abnormalities: certain aspects of the psychological testing; certain liver function tests; glucose intolerance, that is the propensity for diabetes.

So, it is kind of a mixed bag in the variety of statistically significant findings, and I think Dr. Wolfe has listed those pretty well.

I would add a couple of things that have kind of narrowed from 1984 to 1987; and I think that, with the passage of time, the power of the study tends to get a little stronger. And that, I would say, gives me some personal reassurance.

You mentioned the peripheral pulses. There are some tests of thyroid function, reported kidney disease, and abnormal neurologic reflex, and a blood test or so. And those differences where we established statistical significance in 1984 are not apparent in 1987.

What does that mean? I don't think it means very much of anything in the broad context of the study; but that is all in the report, and I think it is easily picked out—not hidden—for anybody to observe.

Mr. **Steinberg**. Thank you. Tony, do you have some questions?

Mr. **Principi**. I have just a few general questions. General, there has been some discussion of testimony received today that the Ranch Handers are not suffering any significant increase in adverse health effects as a result of their exposure to Agent Orange. It would logically follow that those who were exposed on the ground received less exposure.

However, I would like to ask you: What safety precautions did the Air Force require Ranch Handers to take when loading and spraying this chemical compound on the jungles of Vietnam?

General **Sloan**. Specific safety precautions?

Mr. **Principi**. Yes.

General **Sloan**. I think none.

Mr. **Principi**. No gloves?

General **Sloan**. No.

Mr. **Principi**. No showers afterward?

General **Sloan**. No. Well, we did take showers. [Laughter.]

But it was sort of on a random basis because, if we thought there was a very toxic property of Agent Orange, we would not have had them handle that herbicide perhaps the same way we would have them handle it in 1988.

Mr. **Principi**. How were they exposed more to the substance than those on the ground if they never even handled the chemical.

General SLOAN. I guess I misled you. It was all around. They had to clean the tanks; the spray was flying around inside the airplane; the windows were open. Their clothes at times would be drenched in the herbicide.

And as a matter of fact, the enlisted ground troops seem to be the ones that most likely fell into that category. The enlisted ground troops and the Ranch Hand folks; maybe that is where I misled you.

Mr. PRINCIPI. Perhaps I am not understanding you correctly. You stated that the Air Force knew that this was a toxic substance, and that is why you did not allow the service personnel to handle it. You are saying that they were, in fact, all around it. They were sometimes cleaning out tanks, but there were no required safety precautions for those who may have been exposed to it. I don't understand.

General SLOAN. We though it was essentially a safe substance at the time. With your permission, Major Spey is here, and he had actual experience. Perhaps he could help us with this interpretation.

Mr. PRINCIPI. Would you identify yourself for the record, please?

Major Spey. My name is Maj. Jack Spey, U.S. Air Force, retired. I served for 6½ years in Indochina during that conflict, 3 years in Laos and 3½ years with Operation Ranch Hand as a pilot and instructor pilot.

I later spent 4 years instructing replacement spray pilots going to Vietnam.

There were no unusual safety precautions used by the air crew, flight crew, or ground loading personnel because there was no need to. We were spraying agricultural herbicides that were believed to be safe and are still believed to be safe.

The ground personnel probably had the highest degree and frequency of contact with the herbicides as a result of loading aircraft, repairing and maintaining damaged aircraft, preparing spray tanks, et cetera, et cetera, et cetera. So, I just wanted to assist the general on that particular point.

The flight crew flew in ordinary combat fatigues. Due to the temperature, quite often we flew in just T-shirts with a flak jacket over the T-shirts, with the front windows of the aircraft open, to put it in an operational context—for the counsel—so that you can better appreciate not only the flying environment but the ground environment as well.

Mr. PRINCIPI. General, one further question. During the course of your testimony, you said we could be reassured by the results of the Ranch Hand studies to date. Is that generally a correct statement?

General SLOAN. Yes, sir. That is my personal opinion.

Mr. PRINCIPI. Do you think that is true even though there are some findings regarding a significant statistical increase in certain systemic cancers in enlisted personnel and also in birth defects?

General SLOAN. I do. In my own mind, I am not convinced that there is a birth defect problem. As a matter of fact, we have seen—and I think we have talked about that in sufficient detail—where the committee is knowledgeable of the difference between reported and verified birth defects.

While reported birth defects are of some interest and might lead to verification, that is really where it is. Verifying birth defects is what the real answer is. It gets rid of the phenomenon of under and overreporting. We haven't done that yet.

I am not convinced that we have any birth defect problem. As a matter of fact, to me the information just released by the CDC is reassuring; and they found the same thing. They found an excess of reported birth defects. When they looked at it by verification, that difference went away.

I understand that it is important to consider the mind-set of the people who are reporting the defects; and I understand that people who were in the Ranch Hand group initially thought they might well have a higher likelihood of birth defects.

And I understand we can provide that for you about a year from now when that study is complete.

Mr. PRINCIPI. One very quick, final question. In order to ensure total scientific and intellectual freedom in finding answers to these questions, the Congress requested that CDC, as opposed to the VA, undertake much of the research. Do you feel that there has been total scientific and intellectual freedom, to avoid the perception of governmental interference?

Do you feel this that is true within the Air Force as well?

General SLOAN. I think you see an example of that at this table. I can't imagine, if that were not the case, where on Air Force stationery, Dr. Albanese has reported his findings.

Mr. PRINCIPI. Dr. Albanese, do you agree with that statement?

Dr. ALBANESE. I am definitely very, very grateful that the Air Force gave me the opportunity to look at the data. I feel very warm about it. I think the Air Force has given me every intellectual opportunity to pursue this issue.

Mr. PRINCIPI. I think that, in and of itself, should be very reassuring to veterans. Thank you very much.

Mr. STEINBERG. Just a final question to follow up on Tony's inquiry. Would you say, in light of what was described as the normal procedures that pertained with respect to the spraying, that there is some reasonable similarity between the Ranch Hands' spraying conditions and the agricultural workers that are studied in the various studies that we have talked about this morning and will be talking about with the next panel?

Is there some reasonable parallel there?

Dr. WOLFE. I think there is a parallel. We have not looked into that in any depth, but I think those studies in Kansas are more applicable to our study than to the general group of ground troops.

General SLOAN. You have heard a couple of observations that there are significant differences. The battle damage, leaking herbicides and that sort of thing; and I guess you will hear later that these are possibly the subject of further study.

Mr. STEINBERG. Let me try to clarify one other thing, with respect to the verification of reported birth defects among the Ranch Handers. Have all of the positive reports of birth defects been verified at this point?

Dr. WOLFE. No, sir. And we haven't broken the code yet. It is still in the computer; there are 6,000 records, and we don't expect the analysis of all those records to be completed quite yet. And then, the analysis of that will require another few months, and that brings us to the June 1989 time frame.

Mr. **STEINBERG**. Are you verifying both positive and negative reports?

Dr. **WOLFE**. Yes.

Mr. **STEINBERG**. And you have not completed either?

Dr. **WOLFE**. Correct.

Mr. **STEINBERG**. Dr. Michalek?

Dr. **MICHALEK**. The positives were looked at first, and I believe there was a 65 percent ascertainment back in 1984. These things take a long time with missing records and the difficulty in locating people.

Dr. **WOLFE**. We have proceeded with the verification. Our people are gathering the records and reviewing them. We are doing this in the blind. They do not know the group status of the fathers, and they do not know the health status of the child's records that they were dealing with.

I believe that they have not completed 100 percent verification of either group.

Mr. **STEINBERG**. Is that the Air Force's testimony? That the verification of birth defects, both positive and negative, is ongoing?

Dr. **WOLFE**. Yes.

Mr. **STEINBERG**. Thank you very much, gentlemen. We appreciate your bearing with us so long.

Would the next panel please come forward? Dr. Sheila Zahm, Epidemiologist, with the National Cancer Institute; Dr. Donald Barnes, Science Advisory Board Director, Environmental Protection Agency; and Mr. Robert Long, Deputy Assistant Secretary for Science and Education, Department of Agriculture.

We welcome all of you. We appreciate your having borne with us this long morning, now entering the afternoon. Consistent with what Senator Cranston requested, we will withhold your direct testimony until he returns or another member returns, and I will ask some questions that he intended to ask of the panel.

I believe it is correct, Dr. Zahm, that you do not have a direct statement?

TESTIMONY OF DR. SHEILA ZAHM, EPIDEMIOLOGIST, NATIONAL CANCER INSTITUTE

Dr. **ZAHM**. That is correct. I have a statement from the National Cancer Institute to be inserted in the record.

[The prepared statement of the National Cancer Institute appears on p. 258.]

Mr. **STEINBERG**. We have a number of questions for you. We understand that NCI has four ongoing studies regarding the health effects of herbicide exposure.

Could you describe for us briefly each of the studies, including the type and size, the oversight components involved, the diseases which are being evaluated, and the status of the research efforts, including the expected completion dates?

Dr. **ZAHM**. There are four ongoing studies. Two of them are very similar in design. We are studying particular types of cancers and a control group from the general population, and we have asked about their farming history and pesticide exposures.

One of those studies is being conducted in the State of Nebraska. That study has 385 non-Hodgkin's lymphoma cases, 75 Hodgkin's disease cases, 56 chronic lymphocytic leukemia cases, 72 multiple myeloma cases, and approximately 1,400 population controls.

Preliminary results from the study suggest that there is an association between herbicides and non-Hodgkin's lymphoma, although not as strong or dramatic as we have seen in the Kansas study. We hope to have a report available by this year's end.

Mr. STEINBERG. Is there any dioxin involved in that study?

Dr. ZAHM. The herbicide involved is primarily 2,4-D, not 2,4,5-T. 2,4-D has certain dioxins isomers in it, but not the 2,3,7,8-TCDD isomer which is considered the most toxic and carcinogenic.

Mr. STEINBERG. So, that study is quite similar to the Kansas study?

Dr. ZAHM. Yes, very similar. The second case-control study involved 622 non-Hodgkin's lymphoma cases, 578 leukemia cases, and 1,245 controls, and was conducted in Iowa and Minnesota. Preliminary results from this study showed a nonsignificant association between non-Hodgkin's lymphoma and 2,4,5-T use, but no association with 2,4-D use.

Mr. STEINBERG. Do I understand you correctly that you did not find any excess NHL up to this point?

Dr. ZAHM. Looking just at ever/never exposure or years of use, there was no association. However, the study did not initially collect information on days per year of use, the variable of importance in the Kansas study. Efforts are underway to recontact the herbicide users in the study to obtain that information. The results should be available within a year.

The other two studies which are under way are not agricultural studies. They are applicator studies. The first is a study of approximately 30,000 ChemLawn applicators. These men can be exposed to herbicides, specifically 2,4-D, on a daily basis for about 90–120 days per year. We expect to complete abstracting the occupational records and pesticide program data next month. Then, we will trace the cohort to determine vital status and make comparisons with the general population. Results should be available in 1½–2 years.

Mr. STEINBERG. There are no preliminary data?

Dr. ZAHM. No. The fourth study involves employees of County Noxious Weed Departments. These men are county employees who spray herbicides on public and private lands on weeds that are particularly difficult to control. We are currently conducting a pilot study in Kansas. Although the group is much smaller than the ChemLawn group—only about 2,000—the program is an old one. Many applicators are long-term employees with exposures dating back 30 years. To increase the numbers we are exploring the possibility of expanding the study to other states in the Midwest.

Mr. STEINBERG. Thank you very much. If I may, let me just apologize for not welcoming Dr. Philip Kearney, Associate Area Director for Natural Resources of the Agricultural Research Service of the Department of Agriculture, who is accompanying Mr. Long. We welcome you, Dr. Kearney.

At this point, the chairman has returned, so Dr. Barnes, would you please proceed with your direct testimony?

STATEMENT OF DR. DONALD G. BARNES, ACTING DIRECTOR, SCIENCE ADVISORY BOARD, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. BARNES. The Agent Orange is a mixture of two herbicides—2,4,5-T and 2,4-D. Both of these individual compounds are herbicides which were once used in the United States.

In 1980, the use of all 2,4,5-T in this country was cancelled. The herbicide 2,4,5-T in the United States was registered for a variety of uses and contains the potent dioxin contaminant 2,3,7,8-TCDD. 2,4-D does not contain this particular form of dioxin.

As you know, in the 1970s, in connection with a cancellation hearing on 2,4,5-T, the Environmental Protection Agency developed a risk assessment on 2,3,7,8-TCDD, or dioxin, regarding its ability to cause cancer in laboratory animals and, by extrapolation, possibly cause cancer in humans as well.

Interpreting the data in regard to human exposure and possible toxicity has been very difficult, as you all know. Many millions of dollars of studies have been conducted to try to assess what the data really mean. And if you look at the conclusions that various groups have drawn—by the United States, or agencies within the United States, or governments across the world—the interpretation of these same data have spanned a wide range. Just in terms of 2,3,7,8-TCDD as a major carcinogen, nations across the world differ by as much as a thousandfold in terms of their interpretation of how potent this chemical really is.

In 1986, the Administrator of EPA asked Agency scientists to develop an updated position on the potency of dioxin, to see if there ought to be some change based upon four factors. First, development of new scientific data available from the early 1980s. Second, recent data that suggest that there are background levels of the 2,3,7,8-TCDD in tissues of humans around the world.

Third, the wide range of official views on the potency of dioxin; and finally, the apparent discontinuity between estimates that are extrapolated based on animal experiments and the results observed in exposed human populations.

In an initial draft of that update was circulated for limited peer review last fall. The assessment should be available for review by Congress and the public after it is officially sent to our Science Advisory Board later this spring.

The Science Advisory Board is a constituted body of outside independent scientists that help the Agency assess the scientific basis for its regulations and standards. Only after it is reviewed by the Science Advisory Board will EPA proceed to prepare a final position on the toxicity of 2,3,7,8-TCDD.

Chairman CRANSTON. Thank you very much. Mr. Long, I gather you have a statement?

Mr. LONG. Yes, I have, Mr. Chairman.

[The prepared statement of Dr. Barnes appears on p. 268.]

STATEMENT OF ROBERT W. LONG, DEPUTY ASSISTANT SECRETARY, SCIENCE AND EDUCATION, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY DR. PHILIP KEARNEY, ASSOCIATE AREA DIRECTOR FOR NATURAL RESOURCES, AGRICULTURAL RESEARCH SERVICE

Mr. LONG. Mr. Chairman, I am pleased to be here. Dr. Philip Kearney is here with me, and he will be able to answer questions you may have. A full text has been prepared, and I will just give a brief overview.

USDA's major inputs into the Agent Orange issue have been in the environmental area, particularly in the fate and the behavior of 2,4-D, 2,4,5-T, and the dioxin impurity TCDD in soils, plants, water, farm animals, and some limited studies on worker exposure to these herbicides.

We first did research on 2,4-D at the Beltsville Agricultural Research Center shortly after World War II. Subsequently, we examined the effectiveness of herbicide 2,4,5-T for brush control on pasture, rangelands, and rights-of-way.

Over the decade following World War II, ARS expended considerable research effort to examine performance of the phenoxy herbicides in a number of agricultural cropping systems.

Around 1963, we entered into an agreement with the Department of Defense to conduct research on defoliation of vegetation in tropical and subtropical habitats. At that time, we used a mixture of herbicides containing 2,4-D and 2,4,5-T which are the herbicides in Agent Orange.

We found that this mixture was extremely effective in defoliating vegetation in tropical and subtropical areas. The objective of this research was to reduce our casualties in Vietnam due to enemy ambush.

The disclosure in 1969 that 2,4,5-T caused birth defects in rats and mice and the subsequent disclosure that the 2,4,5-T samples used in these studies contained substantial amounts of the potent dioxin impurity, TCDD, responsibility for these birth defects have figured in the Agent Orange debates that have lasted almost two decades.

Our scientists attended meetings with the Surgeon General shortly after these exposures. At that time, we made a commitment to learn more about TCDD, the most toxic form of dioxin found in the phenoxy herbicides.

In 1970, ARS initiated a major research project in this area. The survey of pesticides for dioxin content was completed in 1972. By 1973, most of the results of this research had been published. In brief, the dioxin TCDD was found to be stable in the environment, with no detectable leaching, no biosynthesis in soils, and virtually no uptake by plants. Dioxin was accumulated by aquatic organisms and was very toxic to fish.

In the ensuing years, the U.S. Department of Agriculture was represented on the Veterans' Administration Advisory Committee on Health Related Effects of Herbicides and on the White House Agent Orange Working Group. We also had a representative on the Scientific Panel in the White House Working Group.

USDA scientists, our cooperators in the university system, and agricultural trade associations were involved in several studies that were a part of the total scientific effort being tracked by the White House Agent Orange Working Group.

Reports of these studies have been published and can be made available.

In the 1980s, we worked closely with the Canadian Government when it was discovered that a dioxin isomer less toxic than TCDD was detected in 2,4-D. We have worked closely with Dr. Aaron Blair, Chief, Occupation Studies Section, and his coworkers of the National Cancer Institute on the protocols for a study on the use of herbicides and the incidence of cancer among farmers in the State of Kansas.

The results of this study were reported earlier. We are now cooperating with Dr. Blair by reviewing protocols on a second proposed study.

Our scientists have recently attempted to answer the difficult question concerning potential human exposure to TCDD and related chemicals in soil. This activity originated when other agencies requested assistance in evaluating the TCDD episode in Missouri and the PBB contamination in Michigan.

Much of the data we have collected is from surrogate animals and chemicals other than TCDD. We believe this research may have some bearing on the question of exposure of our combat personnel in Vietnam, when they moved into a previously sprayed area.

We appreciate the opportunity, Mr. Chairman, to appear before this committee, and we would be pleased to answer any questions relating to our testimony or to provide any information that is available to the committee.

Chairman CRANSTON. Thank you very much.

[The prepared statement of Mr. Long appears on p. 277.]

Chairman CRANSTON. I am not quite sure which questions Jon Steinberg asked in my absence. So, there will be a moment's wait until he gets back.

I would like to get back to you again, Dr. Zahm, with some questions. If you can, be brief and precise in your responses. Will any of the National Cancer Institute's ongoing studies be able to provide evidence regarding dioxin, in your opinion?

Dr. ZAHM. The NCI agricultural studies deal primarily with exposure to 2,4-D, which does not have high levels of the very toxic dioxin isomer 2,3,7,8-TCDD, which occurs in the herbicide 2,4,5-T and is of most concern with regard to cancer. There is some 2,4,5-T exposure in the midwestern States where our studies have been conducted, but not very much. Consequently, the studies cannot address dioxin per se.

Chairman CRANSTON. What are the differences, Dr. Zahm, in the nature of the herbicide exposure which could be received occupationally as compared to the nature of the exposure in Vietnam?

Dr. ZAHM. I think there were probably substantial differences in the dose, the frequency of exposure, the duration of exposure, and certainly the contaminants that were in the solutions. The effect of these differences on the subsequent risk is not known.

Chairman **CRANSTON**. If you could expand on that for the record, I would appreciate it.

Dr. **ZAHM**. Sure.

[Subsequently, Dr. Zahm furnished the following information:]

COMMENT ON THE DIFFERENCES IN THE NATURE OF HERBICIDE EXPOSURE WHICH COULD BE RECEIVED OCCUPATIONALLY VS. VIETNAM

The primary herbicide exposure of the farmers and the applicator groups is 2,4-dichlorophenoxyacetic acid (2,4-D). Agent Orange, used in Vietnam, was a formulation of 50 percent 2,4,5-Trichlorophenoxyacetic acid (2,4,5-T) and 50 percent 2,4-D. Despite the apparent commonality of exposure, the nature of the exposures may differ widely. First, the occupationally exposed persons in the National Cancer Institute studies usually mixed and applied herbicides themselves while most Vietnam veterans were not involved with these operations. The veterans who were directly involved with Operation Ranch Hand might have handled Agent Orange in similar manner as farmers or professional applicators, but other ground troops did not. Further, the occupational and Vietnam scenarios may differ widely with respect to formulation, dose, frequency of exposure, duration of exposure, carrier solvents, contaminants, method of application, use of protective equipment, climatic conditions, other possibly hazardous exposures and conditions, and lifestyle factors, which could affect subsequent risk in unknown ways. For example, many farmers or professional applicators use tractor-mounted and handheld sprayers which can result in higher dermal exposures than persons indirectly exposed from aerial spraying. On the other hand, farmers and applicators may have been able to wash and remove contaminated clothing more promptly than exposed soldiers in Vietnam. Farmers and applicators may work in their jobs for many more years than the veterans' average tour of duty in Vietnam. The humid, tropical environment of Vietnam may have affected degradation of 2,4-D, 2,4,5-T, and dioxin so that exposures would differ in the more arid, less forested mid-western area of the United States. Many other examples of difference could be cited. We do not know how any or all of these differences affect the relevance to the veterans of the occupational findings of increased risk of non-Hodgkin's lymphoma. Caution must be taken when generalizing the results to the veterans.

Chairman **CRANSTON**. What significance do these differences have with respect to evaluating studies of exposure in one group as compared to the other group?

Dr. **ZAHM**. I think the findings of excess cancer risk in farmers certainly raises concern for the veteran, but we just do not know the effects of the differences in the exposure scenarios.

Chairman **CRANSTON**. What relevance do you believe the Kansas study has with respect to veterans' exposure to Agent Orange in Vietnam?

Dr. **ZAHM**. 2,4-D exposure was associated with a non-Hodgkin's lymphoma in the Kansas study. The highest risk was seen in farmers who mixed or applied the herbicide themselves. The veterans involved with the Ranch Hand operation mixed and applied Agent Orange—50 percent = 2,4-D—and may have somewhat comparable exposures as the Kansas farmers. Our findings might be quite relevant for them. The findings may not be as relevant for the ground troops who were exposed "second-hand", if you will. In fact, the Kansas study showed virtually no excess risk in men on farms where herbicides were used but who did not mix or apply the herbicides themselves.

Chairman **CRANSTON**. As you are aware, the CDC Agent Orange Exposure Study was cancelled by the executive branch since exposure levels couldn't be determined. In the Kansas study, exposure was determined based on self-reported information, which the CDC has found as to Vietnam veterans doesn't correlate with actual exposure.

Have you been able to verify exposures in the Kansas study; and if not, what does that mean with respect to interpretation of the study results?

Dr. ZAHM. I have a two-part answer on that. First of all, the ability of the farmers to recall their pesticide exposures is quite good. These farmowners decide what to apply, purchase the chemicals themselves, and apply the chemicals themselves. The fact that pesticides are expensive and tax-deductible also helps farmers to remember what was used. This awareness of exposure on a farm is very different from whether a veteran can determine whether he was sprayed with Agent Orange.

Second, we are initiating a study right now to try to validate interview data on pesticides using reinterviews, available records, air measurements and biological monitoring. The recently developed blood test for dioxin was not available when we did the Kansas study.

Chairman CRANSTON. How will exposure information be determined and verified in the four ongoing NCI studies?

Dr. ZAHM. In the two studies of applicators, we are actually obtaining the exposure data from occupational records which preexist any adverse health effects. So, there are no recall problems in those two studies.

The other two studies, which are case-control farming studies, are based on interview data. So, there may be some recall limitations. However, we tried to evaluate this problem in the Kansas study. We contacted pesticide suppliers to verify the information that the farmers had given us in the interviews. We found there were no major differences and recall between the cases and controls. The data may not be completely accurate, but it is not biased with respect to case-control status. If there's no bias, the risk estimates can only be underestimates, not overestimates.

Chairman CRANSTON. OTA states on page 7 of its testimony, in reviewing the Western Washington study that, "The lack of association overall of NHL with specific high levels of potential exposures leaves considerable doubt that chlorophenols or phenoxy herbicides alone were responsible for the excess, but that possibility still exists."

Do you agree with that statement? And if so, how would you reconcile that with your findings in the Kansas study?

Dr. ZAHM. The Washington study did not have a lot of the information that we had on the amount of exposure to herbicides. The Washington analyses were solely based on job title, for example, forester or farmer.

When we looked at our data using general job titles, we also don't see much of an association. It is only when we look at the subgroups, for example, farmers exposed many days per year, that we can see the increased risk. So, in my mind, the Washington study used too general an approach, and I am not surprised that it shows no association. Detailed exposure data are needed.

Chairman CRANSTON. The next question is a question for all three of the panelists; and I would like to ask Dr. Zahm to comment first. The OTA states with respect to the Kansas study that, "While 2,4-D was the exposure of interest in this study and the most common, it was not the only one, and it is possible that the association with NHL is a consequence of one or more of the other herbicides. It is not possible to disaggregate the effects of single herbicides in this population because exposures to only one chemical were rare."

So, first, Dr. Zahm, do you agree with that? And please explain briefly, and you have been very brief so far. Thank you.

Dr. ZAHM. I agree that farmers are indeed exposed to multiple pesticides. It is very rare that someone uses just one. However, we collected complete histories; we asked about every herbicide and insecticide that the farmers used.

We went to great pains to analyze the effects of multiple exposures, and found that no other herbicide class or insecticide accounted for this 2,4-D finding. Risk of NHL was strongest in the 2,4-D exposed group.

Chairman CRANSTON. Dr. Barnes, would you comment on the OTA analysis?

Dr. BARNES. My recollection is that the study done by the NCI had tried to look at this in some exquisite detail by looking at the amount of herbicide purchased and used in the area of the study. So, at least they made an attempt to verify the exposures to humans.

Chairman CRANSTON. So, you agree that it is not possible to disaggregate the effects of single herbicides because a number of chemicals were used?

Dr. BARNES. Certainly, in any study it is difficult or impossible to remove all confounding factors. However, in this case, they did make an attempt to do so. One of the first ways to do this is to go to Kansas where they spray the wheat, and 2,4-D is one of the most prevalently used herbicides in that area.

Chairman CRANSTON. Mr. Long, do you have a comment on the OTA study?

Mr. LONG. No, Mr. Chairman.

Chairman CRANSTON. Dr. Barnes, what is the strength of the causal association required before the EPA will label a substance "carcinogenic"?

Dr. BARNES. We have a classification—by the weight of the evidence. And there are five different categories of toxins.

Number one is a known human carcinogen; and for that statement, we must have validated epidemiological studies which clearly show the association between chemical exposures to humans and cancers. Basically, the same approach is used by the International Agency for Research of Cancer. Some 26 chemicals fall into that class.

And we have a second class, which is called Class B, for which there generally are validated animal tests which show cancer in laboratory animals. And there may be some epidemiological evidence that may suggest carcinogenic effects in humans, but it is limited in scope. That is the second class.

The third class is where you have no human evidence at all but some evidence in the animals, but it is not very definitive. You can argue that the data we have seen on 2,4-D falls into the fourth category, which is an inconclusive class. We have seen the data published thus far in terms of effects of 2,4-D on humans; we have looked also at animal studies, which we have asked the manufacturers to perform and have been reviewed by our outside scientific panels.

In the view of the outside panels, reviewed and confirmed by the Agency, we don't see at this time that the data are sufficient for us to conclude that there is either animal carcinogenicity or human carcinogenicity.

Chairman CRANSTON. Why is the EPA considering reducing its assessment of the cancer-causing potential of dioxin?

Dr. BARNES. As I stated in my testimony, there are four factors we are looking into. Number one is new data that have come forward since our 1985 position. The second is the fact that we now know that there are human body burden of 2, 3, 7, 8-TCDD in the population, and the people are therefore being exposed to some degree.

And the question is: If we are all getting exposed to dioxin to some degree, is the incidence of cancer the same in the population, consistent with the predictions we would have made based upon results seen in the animal studies? That apparent discontinuity or disjuncture between the human and animal results has been a cause of some people's concern.

And third, as I say, agencies around the world have used the same data base and have inferred different conclusions. So, the Administrator asked us to take a look at that to see whether or not the EPA position is one that is consistent with all of the data.

Chairman CRANSTON. Would you describe how long dioxin persists in the environment, including the factors which affect such persistence?

Dr. BARNES. I would say first that the persistence of dioxin in the environment depends clearly on what conditions it experiences in the environment. There are certain conditions of sunlight and certain other associated conditions that are relevant.

Generally speaking, however, it is fairly persistent. For example, we have just completed what we refer to as——

Chairman CRANSTON. May I interrupt for a moment? I have to go to another roll call, and Jon Steinberg will carry on until I get back. Thank you.

Mr. STEINBERG. Please proceed.

Dr. BARNES. We have completed a national study where we have gone back to sites in the United States where we thought dioxin might have been used or where there were spills, and have looked for dioxin many years afterward and have been able to detect small amounts of this chemical in the environment.

Experiments have been done in which dioxin was buried under 10 inches of soil, out of sunlight and has remained practically unchanged for decades. So, it is persistent in the environment. There are a few bugs that will chew it up but not many.

Under certain conditions however, it can in fact decompose, rather rapidly in the presence of sunlight.

Mr. LONG. Dr. Kearney might want to comment on that.

Mr. STEINBERG. Dr. Kearney, do you want to comment?

Dr. KEARNEY. Yes. We did experiments on this in the early 1970s in which we put three concentrations of dioxin in two different soil types, and we found the material to be extremely persistent—some for 10 to 12 years. So, it is a very persistent, stable substance.

Mr. STEINBERG. Do either of you have a comment on how long it would endure on foliage?

Dr. KEARNEY. This was an issue that arose in the—of much of the dioxin that had landed on trees. There is a time when photodecomposition is important in the breakdown.

When the leaves fall, then you have a secondary source which is much more stable; but on the leaf surface, it is subject to some photodecomposition breakdown.

Mr. STEINBERG. Again, either for Dr. Barnes or for Dr. Kearney, could you explain the various means by which the human body can absorb dioxin from the environment? And what factors could prevent absorbed dioxin from being retained?

Dr. KEARNEY. Let me take a crack at it first. We were concerned in Michigan in the PBB incident that, when a farmer removed his cattle, when all the feed was disposed, and when he put new cattle back on those lands, the animals again were showing residues of PBBs.

We then tried to find out what the source of this was, and apparently the soil still contained PBBs; and the feeding habit of the animal was such that the animal actually consumed soil in its grazing habit.

And we found out that anywhere from 1 to 5 percent of the diet of the animal is actually soil itself. If that soil is contaminated, then the animal can bioconcentrate that material. We think that this is one of the major routes of exposure, that is, human ingestion.

We then looked at situations where we used—and unpaved lots. We fed the animals supplemental feed, and it appears that dermal exposure is a less important route than actual consumption.

Dr. BARNES. I would concur with that; another route of exposure that has been of expressed concern is the air route.

The ingestion route seems to be somewhat greater than the dermal route but not by much.

I mentioned earlier in my testimony that there are human body burdens that suggest that somehow or another we are, in our society, being exposed to dioxin and retaining it in our bodies. The conventional wisdom at this point—although not proven, but a strong case has been made for it—is that our exposure is occurring somehow through the food chain. What the sources are and how it invades the food chain are unclear at this point.

Mr. STEINBERG. But there is no scientific data with respect to ingestion?

Dr. BARNES. Certainly, there is in terms of feeding animals. There have been some identified food sources obtained that have low levels of dioxin. So, this could be a source.

Mr. STEINBERG. You might have it, for example, on fruit that had been sprayed, not perfectly clean before it was eaten?

Dr. BARNES. I am not aware of any data on that.

Mr. STEINBERG. No data on that?

Dr. BARNES. There was some data a few years ago from Canada regarding apples, but that disappeared under closer scrutiny.

Mr. STEINBERG. Dr. Kearney, do you want to comment on that?

Dr. Kearney. There was some data in which cows were grazing in a field that was being sprayed with 2,4-D; and there was some evidence that you could get very low levels of TCDD in the milk from those animals.

Mr. Steinberg. From the grasses?

Dr. Kearney. From the grasses they were consuming.

Mr. Steinberg. What about water supply?

Dr. Kearney. I don't think that is a very major route because the compound is extremely insoluble. It is certainly less than a part per million; and, therefore, it would tend to be not a major route.

Dr. Barnes. I would add that 100 samples of the drinking water have been analyzed; and as far as I am aware, there have been only a few which are "positive," but in most cases those have been situations in which there may have been sediment associated with that water. So, the dioxin was associated with a particular matter and not the water itself.

Mr. Steinberg. I don't believe you commented on what factors might prevent retention of dioxin in the system?

Dr. Kearney. To prevent its absorption?

Mr. Steinberg. Once it is absorbed, to prevent it from being retained in the body. Are there factors that deal with that?

Dr. Kearney. I don't think so. There are physiological factors which affect the movement of the chemical in the body in its storage sites; but once it gets in there, all you can do is essentially control it.

Dr. Barnes. And the half-life, as we indicated earlier, is long, about 7 years or so.

Mr. Steinberg. Dr. Zahm, do you have anything you wish to add to this?

Dr. Zahm. No.

Mr. Steinberg. Tony, do you have any questions for the panel?

Mr. Principi. No, I don't.

Mr. Steinberg. We thank you all very much for bearing with us so long. We apologize for the hearing's length.

Now, I would like to call forward and welcome Ms. Hellen Gelband, Senior Analyst at the Office of Technology Assessment; a long-time friend and past National Commander of the DAV, Mr. Oliver Meadows, who is Chairman of the Veterans' Advisory Committee on Environmental Hazards of the Veterans' Administration, and Dr. Armon Yanders, who is a member of the Scientific Council of that advisory committee.

We are delighted to have all of you here today. We welcome you to this committee. What I would propose to do until the chairman returns is to ask some questions.

Oh, I am sorry. Mr. Fred Conway, you are also accompanying Mr. Meadows, and we welcome you.

I have some questions to pose, and then we will go into your direct testimony when the chairman returns.

Let me clarify for the record—which I am sure you were about to do, anyway, Hellen—in terms of the Air Force testimony, we will place it in the record at the appropriate point in the course of the Air Force testimony the OTA letter from Dr. Gibbons, dated May 6, 1988, to Senator Cranston—and I am sure that there similar letters also sent to Senator Murkowski, Chairman Montgomery, and Representative Solomon—reporting the review made by OTA of the protocol for the Ranch Hand proposal to carry out the blood dioxin study.

As I have indicated, the OTA has indeed given its approval and indicated specifically that there is no reason for not beginning the tests. Somehow or other, this word has not gotten to the Air Force; and we intend to bridge that gap and make sure that they get it.

Now, let me go to some questions, if I may.

First, Hellen, although the NCI's Kansas study found a two-fold increase in the risk of NHL associated with herbicide use, the larger Western Washington study on the occurrence of soft tissue sarcoma and NHL in relation to various occupational and educational distributors, did not find any overall association with NHL.

What do you believe is the significance of those differences? And I will ask Dr. Yanders to comment on that as well.

Ms. GELBAND. I think Dr. Zahm characterized the differences quite well. The exposure measures used in the Washington study were rather crude. I think one of the things it emphasizes is the importance of having good exposure information. Comparing the Washington study to the Ranch Hand study, for example, exposure information was probably much less accurate. Just asking people: Were you ever a farmer; did you ever spray herbicides; is not going to yield the best information.

On one of their measures, they did find a slightly increased risk of non-Hodgkin's lymphoma; but it was very small, and it was small enough to be caused by any number of recall biases. I do think that the Kansas study was better defined, with more exposure information.

Mr. STEINBERG. Dr. Yanders, do you wish to comment on that?

Dr. YANDERS. I would concur completely with what Ms. Gelband said. The dangers that are implicit in the kinds of recall studies that we are talking about here are well known in epidemiology.

I think I would concur with her conclusion that the Kansas study is the better of the two because of the ways that this kind of bias was compensated for.

Mr. STEINBERG. This question would be for all three of you.

The VA Proportionate Mortality Study, the Kansas study, and the Western Washington study have each shown some increased incidence of non-Hodgkin's lymphoma among those studied. Why is it, in your opinion, that they are not enough to be used as a basis for establishing the scientifically acceptable association between Agent Orange and NHL?

Perhaps you would like to begin, Dr. Yanders?

Dr. YANDERS. The association that is seen is a very weak one, to begin with. It is, however, that, although there is no conclusive evidence one way or the other, I think I would have to concur with the statement that was made earlier with respect to non-Hodgkin's lymphoma in general—that the jury is still out.

This is one area in which the Veterans' Advisory Committee on Environmental Hazards would like to see more work done; and it is indeed our understanding that the Veterans' Administration is exploring now a number of research initiatives along this line.

Mr. STEINBERG. Hellen, do you have a comment?

Ms. GELBAND. Yes. The finding of an excess of non-Hodgkin's lymphoma among the Marines in Vietnam was based on a very small number. Although the study was based on 25,000 deaths of Vietnam veterans' this particular finding is based on 35 deaths, of which about 18 may have been in excess of what was expected. That is the basis of this entire debate, I think, in terms of the Vietnam veterans.

There is no information whatsoever about exposure; and looking at the Army results, there was actually a deficit of non-Hodgkin's lymphoma. It was not statistically significant, but it was close. And there seemed to be an unusually low non-Hodgkin's lymphoma rate in the non-Vietnam veteran Marines with whom the Marine Vietnam veterans were compared.

I think it is important that that finding be followed up completely, and I do urge that CDC consider beginning to analyze their non-Hodgkin's lymphoma case control study now rather than later.

Mr. STEINBERG. Oliver, do you wish to comment on this question?

Mr. MEADOWS. It appears to me that the strong signal from the VA Mortality Study of the Marines is that there is something special about the Marine situation. It seems very unusual to me to take a broad group of people, all of which appear to have had the same potential for exposure to Agent Orange, and have one blip on the chart and then say dioxin is involved.

It seems it signals the exactly opposite thing, that there is something extra or different involved, that involves this separate group. I was glad to hear today that there is going to be every effort made—one of the witnesses put forth some of the possible reasons: medication and so forth; but we were certainly glad to hear that there was going to be some effort made to get at any peculiar situation in the service of the Marines that might be an explanation, because you can look at this data either way.

You can say, this indicts dioxin; or you could look at it the other way, and say, there is something special here that has happening that has nothing to do with dioxin. It is purely a matter of viewpoint.

I would like to comment, too, on the Kansas farm study briefly because it is appearing as one of the main studies that is held out as justifying presumptive legislation. I was glad to hear Dr. Zahn here say that they did the best they could to eliminate other exposures among farmers.

But being a farmer myself and having been through this kind of situation with over 40 years of farming, I know that farmers use great quantities of agricultural chemicals, many of which have been branded as carcinogenic. In my own personal experience, I have been all the way through chlordane, lyndane, fungicides of one kind or another, herbicides of one kind or another, and pesticides of one kind or another.

And after a few years they will be taken off the market as being carcinogenic; and then because I happen to be one of those people, I have been wet with weed killer myself, it would be ludicrous to find me dead of cancer at some point in the coming years and say, it was the weed killer experience that killed him. Maybe so and maybe not.

I also put the chlordane down on my new house, so who knows? Farmers use chemicals, and it is very unwise to get too carried away with weed killers or herbicides in this experience because there are too many other complicating factors.

Chairman CRANSTON. Thank you very much, Oliver. And now, I would like you to make your opening statements, provided that you do it in about 4 minutes.

Mr. MEADOWS. How about half that?

Chairman CRANSTON. I have to leave again, and then I will be back again.

Mr. MEADOWS. Yes, I will be quite brief.

STATEMENT OF OLIVER MEADOWS, CHAIRMAN, VETERANS' ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS, ACCOMPANIED BY DR. ARMON F. YANDERS, MEMBER, SCIENTIFIC COUNCIL; AND FREDERIC L. CONWAY, III, EXECUTIVE SECRETARY

Mr. MEADOWS. We have a prepared statement that we have given you, but I will remind you that you set us up by law. There are 15 of us, 4 lay people and 11 scientific people; and there seems to be some misunderstanding about what we do and what we are supposed to do.

Our principal job is to review the regulations of the VA and to look at issues and questions and research that are pointed in our direction by the Veterans' Administration or other sources. Now, in our period of operation, we have had questions posed to us by members of the House, by members of the Senate, by the Administrator of Veterans' Affairs, by the Chief Medical Director, the Chief Benefits Director, and the Chairman of the Board of Veterans' Appeals.

And when we get those specific questions, we try to give them priority attention. In addition to that then, we sort through and try to find the most pertinent literature on the subject and evaluate them and make recommendations to the Administrator and the Congressmen, when they ask us.

We are a group of lay people—four of us; the others are scientific. We are volunteers; we are not a Government agency. We work as a public service for the most part, and we work in almost a vacuum of objectivity.

I want to say for the scientific members of the panel that they are not interested in the politics of this situation particularly. They don't show any interest in the administrative problems of the Veterans' Administration particularly. They are not interested in how much this or that legislative solution would cost.

They apply their scientific expertise to the question at hand, and that seems to be the only interest they have. I think I can say without hesitation that it is an objective group, and we are there to perform the functions you set out for us under the law to try to provide the advice that we are asked to provide.

Now, I have with me Dr. Yanders, and he will talk a little bit more about how we get about looking at this study or that study.

Dr. YANDERS. Thank you, Mr. Chairman. I am happy to be here to testify on behalf of the Scientific Council. The Scientific Council, as I point out in my prepared remarks, does as careful a job as it can in reviewing all the pertinent scientific literature for all sources, no matter from where it comes; whether it comes from the Congress, from the Veterans' Administration, or from veterans' groups.

After there has been a review, there is a complete discussion and a consensus is arrived at within the Scientific Council on whatever reaction the Scientific Council has to that particular bit of evidence or what kinds of recommendations it will make to the whole group.

I might add at this time that consensus occurs after full and complete discussion of the kinds of issues that you have heard talked about today.

Finally, after this review and this discussion, the Scientific Council reaches a consensus, and the entire committee reaches a consensus. I would like to read to you from a couple of statements concerning what we have recommended.

First of all, the Scientific Council is completely unanimous in concluding that there is no scientific or medical evidence to associate adverse health consequences with the exposure of Vietnam veterans to dioxin or to Agent Orange.

In fact, as you have heard this morning, the evidence is accumulating that Vietnam veterans are not at increased risk as a group for disease.

I mentioned earlier in response to a question that there are some areas of interest, especially the non-Hodgkin's lymphoma, but this is something that I would like to see pursued in the form of research.

Regarding the two bills under consideration, it is the consensus of the Scientific Council that the proposed legislation is simply not based on sound scientific evidence. And of course, that is our complete reason for being in existence as the Scientific Council; that is, to provide this body with that kind of advice.

I urge that the committee give very serious consideration to the scientific evidence which is currently available. Certainly, science cannot provide all the answers; it cannot provide the answers to all of your questions; but it can be a source of encouragement in that a great deal of progress is indeed being made.

The evidence that we now have, I think, shows conclusively that Vietnam veterans have not suffered adverse health effects as a consequence of the possible exposure to Agent Orange. Thank you.

[The prepared statement of Mr. Meadows and Dr. Yanders appears on p. 284.]

Mr. STEINBERG. Thank you, Oliver. Hellen, I am at somewhat of a loss now as to what to do. We can defer your statement, if you wish, until the chairman returns and recalls you at that time if you don't mind waiting; and we can go to questions of the next panel. Or we can have your testimony taken at this time, whichever you prefer.

Ms. GELBAND. If you ask me a couple more questions, all my testimony would have been given, anyway. [Laughter.]

Mr. STEINBERG. Let's see if that happens. Let me then begin. This is for the Advisory Committee. The prepared testimony of the Vietnam Veterans of America has presented eight specific criticisms of the Advisory Committee. We will provide you with a copy of that testimony; we would appreciate it if you would provide for the record a detailed, written response to each of those criticisms. If you have a brief response that you wish to make at this time, if you are familiar with that, we would be glad to have it.

Mr. Meadows. Only to reiterate what I said a moment ago, I think there is a broad misunderstanding as to what sort of committee we are and what our functions are. I think we are talking about apples and oranges here, but I will look at this list of criticisms.

[Subsequently, Mr. Meadows furnished the information which appears on p. 300.]

Mr. Steinberg. Do you believe that the Advisory Committee, as currently structured and the resources that are currently made available to it, is capable of fulfilling fully the statutory mission of assessing the value and pertinence of scientific studies the Advisory Committee recommends on?

Mr. Meadows. I believe that it can do an adequate job. If we were looked to to do the basic initial research, obviously it would have to be an altogether different organization; but we are not a research organization. We are simply a group of people trying to look at finished work and review and evaluate studies and say to the Administrator or to the Congress, when the Congress asks us: We believe this does or does not have merit. And that is vastly different from running an investigative operation, such as your witnesses that have preceded us do.

Now, if it wasn't for their activities obviously wouldn't be enough; but under the circumstances, I think we can give adequate advice to the Administrator as to the meaning of various studies.

And I think the four lay members on the committee can do an adequate job for the veterans; I know that is why I am there.

Mr. Steinberg. Dr. Yanders, do you have any views on this?

Dr. Yanders. Only to concur with Mr. Meadows. I think the committee has taken its responsibilities very seriously. Certainly, we have done an incredible amount of reading and reviewing since I have been a member of the council.

And I do believe that the advice that we give is useful to those who request it.

Mr. Steinberg. Has the Advisory Committee ever requested any additional resources from the Agency?

Mr. Meadows. No, we have not. After all, I reiterate that we are a citizens group. Most of our members come and render their services virtually free of charge; they expect no reimbursement for their services in most instances.

To do that, we don't need any additional funds. We have travel, a little bit of travel expense. Those that do collect travel expenses. We don't need any additional resources.

I have no doubt, however, that if we had some little specialized project of some sort and we needed to call on the Administration to furnish backup resources, we could receive those. I don't have any doubt but that they would be most cooperative.

Mr. Conway. If I may, Mr. Steinberg, I would like to state for the record that the Department of Medicine and Surgery, which is the source of our funding, has never ever denied any request for anything required to enable the committee to do its job.

Mr. Steinberg. Thank you. Finally, Dr. Yanders, if you could provide for the record in writing any comments that you have on the testimony which was submitted by Dr. Thomas Gasiewicz of Rochester on behalf of the VVA, we would appreciate that.

We will provide you with a copy of that testimony.

Dr. Yanders. Fine. I have not seen it, but I will be happy to do that.

[Subsequently, Dr. Yanders furnished the information which appears on p. 706.]

Mr. Steinberg. Hellen, we would appreciate the same comments from you as well; and we will make sure that each of you have a copy before you leave.

[Subsequently, Ms. Gelband furnished the information which appears on p. 558.]

Mr. Steinberg. Hellen, what relevance do you believe the Kansas study has with respect to veterans' exposure to Agent Orange in Vietnam? And specifically in commenting on that, what differences do you believe there are in the exposures reported in the Kansas study in relation to ground troops in Vietnam, and how might that affect the significance of the Kansas study with respect to veterans' exposure to Agent Orange?

Ms. Gelband. As others have commented, I think the exposure of Ranch Handers and other small groups in Vietnam—Chemical Corps workers, for example, may have been similar to farmers. But looking at the results of the validation study, it doesn't appear that ground troops, in general, had high exposures. I think CDC did attempt to find people who were in highly sprayed areas for their high exposure group in the validation study; and they found almost no levels above background.

It is hard to conclude that there could have been heavy Agent Orange exposures among ground troops of the type that farmers or applicators would experience. I think it is scientifically unsound to apply results from studies of people with known high exposures to groups of people in whom there is no evidence of exposure.

Mr. Steinberg. Dr. Yanders, do you have a comment on that?

Dr. Yanders. I will have to agree because we are dealing with occupationally exposed people in Kansas and the closest corresponding group among the Vietnam veterans would be the Ranch Handers. What I see as an encouraging prospect for the future is in this remarkable new technique which enables the Centers for Disease Control to look at very low levels of TCDD in the blood serum of individuals.

This, for the first time, is going to give us the possibility of establishing, if one exists, a dose response relationship between the amount of TCDD in the tissues of the person and whatever adverse health effects the person may have.

We are some ways from being there at this time; but as I said, I think for the first time we have some promise of being able to do this. And the dose response relationship is one of the most important bases for making any epidemiological conclusions.

Mr. Meadows. Jon, could I comment further?

Mr. Steinberg. Yes, please.

Mr. MEADOWS. I was glad to see you develop with the Air Force witness the question of financing these further assays that would encompass the entire Ranch Hand group.

There is a snarl in the money picture, as you obviously know; and you were trying to draw out here. We certainly do appreciate the effort that your chairman made and the chairman on the other side made in the first place to get the money for the first pilot group of blood assays lined up; and I think we have a similar problem here that we hope you can help solve again.

Mr. STEINBERG. I know that Senator Cranston and Senator Murkowski and all of us are doing all that we can to work with the Appropriations Committee here to try to find a way in the fiscal year 1988 supplemental—which will be considered in the next couple of months—to see if there is some money from the Agent Orange study itself that had been appropriated and made available to CDC—could possibly be reappropriated or reprogrammed.

I know that Senator Murkowski is supporting this, and I know that we will be making that communication to the Appropriations Committee to see if we can get the approximately $2 million that is needed for that.

I appreciate your raising that issue. Hellen, you stated in your testimony that the ground troops tested in the CDC Blood Validation project "may not be representative of all ground troops." How likely do you think that is and why?

Ms. GELBAND. I really can't describe how likely. When CDC began their Agent Orange study and assumed that they would be able to use military records to identify an exposed cohort, they went to the area of Vietnam where the most troops served in the most heavily sprayed areas.

In fact, there was a lot of spraying in other parts of Vietnam, but the area they chose did seem to have had the most concentrated spraying. It is reported that I Corps had been sprayed very heavily also. I haven't examined the original spray data to verify that.

While CDC tried to target people with high exposures, it is possible that a group somewhere else had higher exposures.

Mr. STEINBERG. But you are also suggesting that they made an effort to find people whom they believed were heavily exposed and who may not be representative of all ground troops——

Ms. GELBAND. I believe that.

Mr. STEINBERG. Dr. Yanders, do you have a comment on that?

Dr. YANDERS. No.

Mr. STEINBERG. All right. Tony?

Mr. PRINCIPI. Oliver, in a letter dated February 11, 1987, regarding the National Cancer Institute's study of Kansas farm workers, you wrote to Senator Murkowski on behalf of the council. You stated that it was your general opinion that the study's findings, while not directly applicable to veterans, did have implications for Vietnam veterans.

Seven months later, the VA released the findings of their mortality study and found what they termed a "significant statistical increase in non-Hodgkin's lymphoma for Marines."

General Sloan, in his testimony this morning, indicated that there is an increased level of birth defects and systemic cancers in enlisted personnel.

Now, based upon this evidence—which may not be conclusive—how can you conclude that evidence is accumulating which shows no adverse health effects on Vietnam veterans exposed to Agent Orange?

Mr. **Meadows**. I will respond to that. That is because the patterns of all the studies that are emerging are almost entirely negative. There is some question to be answered here about the Marines; but by no stretch of the imagination is that conclusive that it relates to dioxin.

The Kansas Farm study is interesting; but the people who are familiar with it just testified to you that it is so complicated by other factors, that it is very difficult to evaluate it. I consider this flimsy evidence, whereas the main stream of the major studies, as they move along, has a very welcome message—so far—and that is that there appears to be little or no association between Agent Orange sprayed in Vietnam and significant increases of disease.

There is a little blip here and there. And then, we touch off an endless debate among the epidemiologists as to what this means and what that means.

But when you look at the major burden of the body of reports in the $100 million you have talked about here this morning that has been spent on various kinds of studies, the answers that are coming back—and they are a little more encouraging all the time and particularly the blood assay, which we consider very significant—gives cause for some substantial hope that we will not have something emerge that will surprise us all.

Mr. **Principi**. Although I disagree with your conclusions, it seems to me that you indicate that the study of the Marines does deserve careful consideration by the Veterans' Administration. Also, in your testimony, you state that the scientific members have expressed frustration that science may never be able to definitively answer the question.

Mr. **Meadows**. I think science is still debating at least some aspects of it.

Mr. **Principi**. Excuse me. The statement is: "that science may never be able to definitively answer the question." If this is the case, is it necessary to say that there is no conclusive evidence to support and cause-and-effect relationship.

Mr. **Meadows**. It will like most other things, I presume. There will never be a total answer on either side of it, but there will be a preponderance of evidence; and that preponderance of evidence is emerging, it appears to us.

Of course, you can always debate that there could be one more group and one more situation, there could be one variation in interpretation. I think you still have people who won't concede that smoking is bad for you; but by now, I think most people believe that the preponderance of evidence is that smoking is bad for you.

There are people paid to pick at studies and question the validity of the scientific studies about smoking. There is no such thing as removing completely every argument that someone can advance about any question, but I think that you will be required to proceed on the basis of where the preponderance of evidence is; and it appears to me that that is quite clear.

Mr. PRINCIPI. Ms. Gelband you state on page 2 of your testimony, that based upon the amount of spray that was likely to have reached the ground and on what is known of the environmental fate of the herbicide components, including dioxin, it appears unlikely that significant exposure would have occurred in that way.

Could you tell me the basis for your statement? What do you mean by "the amount of spray that was likely to have reached the ground"? Did none of this dioxin hit the ground?

Ms. GELBAND. I am sure some of it did. As I understand the usual routine of spraying, in Vietnam there was a triple canopy jungle with three vegetative layers. In order to defoliate an area in general, spraying was carried out three different times, spaced by weeks or days.

On the first pass, most of the herbicide would be held in the leaves of the upper layers, and some of it would filter down to the lower layers of vegetation. But in those first two sprays, according to information released by the Air Force, not very much herbicide—and probably little dioxin—was likely to have actually reached the ground from those sprays.

Some would have reached the ground from the final spray, but they were not spraying pure dioxin, either. We are talking about a contaminant, even though it occurred at higher levels than people thought and higher than we would have liked to have in something that people are exposed to.

Mr. PRINCIPI. A good part of Vietnam was not necessarily jungle, but what we tend to call elephant grass or plains of reeds, which also served as concealment and which there was a good deal of defoliation.

Is that your understanding as well, that they were not only concentrating on triple canopy jungle to defoliate, but they were also defoliating elephant grass—which is 6 to 8 feet high?

Ms. GELBAND. It seems as though most of the Ranch Hand sprays were jungle areas, although I really don't know the exact distribution. I don't know exactly what elephant grass is——

Mr. PRINCIPI. It is very thick, high grass.

Ms. GELBAND. Agent Orange doesn't kill grass. Other herbicides, not containing dioxin, were used to kill the grasses, and, for instance, were used to destroy rice crops as well. But the components of Agent Orange do not kill grasses.

Mr. PRINCIPI. Thank you.

Chairman CRANSTON. Thank you very much. Ms. Gelband, would you make your opening statement, that we may now call your closing statement?

Ms. GELBAND. Sure.

STATEMENT OF HELLEN GELBAND, SENIOR ANALYST, OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS

Ms. GELBAND. Actually, I have very little to add, but I would like to make one comment about the lung cancer findings in the VA Mortality Study. That really is the only lung cancer link that I can find to pending legislation.

The excess occurred only in the Marine veterans, and it is based on a total of about 130 deaths out of the 25,000 deaths looked at, which translates to an excess of about 40 or 50 deaths. That is really what we are talking about; that is the basis for this finding.

It is statistically significant, but there are problems with the proportionate mortality study design. However, since we know the main cause of lung cancer the world over, it would be important to make sure that none of the known causes—particularly cigarette smoking—was the explanation for that finding.

What the VA has done toward finding smoking history among those men is important. But, I think the only way to answer the question adequately is to find out the smoking prevalence in Vietnam veteran Marines and non-Vietnam veteran Marines who are part of that larger, still luring, cohort.

You really can't settle the question by finding out the smoking habits of the people who have already died. It would be very surprising to find out that they didn't smoke, but that is about all you could find out.

The issue of immunosuppressive effects hasn't really been discussed today. I think most of the concern is based on fairly good animal evidence that there are immunosuppressive effects of dioxins. In human beings, thòugh, I know of no studies that actually relate diseases of immunosuppression to exposure to phenoxy herbicides or dioxin.

In the Ranch Hand study and in the CDC Vietnam Experience study, where a large number of laboratory measurements were made of immune function—not even disease, but more subtle markers—there were no differences whatsoever. I think that is quite important.

That is really all I have to add.

[The prepared statement of Ms. Gelband appears on p. 305.]

Chairman CRANSTON. Thank you very much. That concludes the presentations of this panel. Thank you very much. I am sorry I wasn't able to be here.

Now, I will call the next panel. Mr. John Sommer, Director for Veterans' Affairs, The American Legion; Mr. David Gorman, Assistant National Legislative Director for Medical Affairs, DAV; Mr. John C. Bollinger, Associate Legislative Director, PVA; Mr. Gordon Thorson, Special Assistant to the Director of the National Legislative Service, VFW; and Ms. Mary Stout, President, VVA, accompanied by Dr. Thomas A. Gasiewicz, Associate Professor of Toxicology, Department of Biophysics, University of Rochester, New York. Mr. Sommer, if you would lead off, please?

STATEMENT OF JOHN F. SOMMER, JR., DIRECTOR, NATIONAL VETERANS' AFFAIRS AND REHABILITATION COMMISSION, THE AMERICAN LEGION

Mr. SOMMER. Thank you, Mr. Chairman. The American Legion would like to thank you for scheduling this hearing on the issue of Agent Orange. Many things have transpired since the last hearing on this important issue, yet little progress has been made in determining the health effects of Agent Orange exposure to Vietnam veterans, at least those that the Government will accept.

With respect to the legislation that is under consideration today, we, in general, support its enactment. The American Legion fully supports the establishment of a presumption of a service connection for non-Hodgkins lymphoma based upon exposure to Agent Orange. We feel that there is adequate scientific evidence on which to base such a presumption.

In the case of lung cancer, while we do not oppose the establishment of presumption, we feel that there is a need for some clarification with respect to causation and the types of cancer that are indicated.

We definitely support the mandating of an agreement between the VA and a scientific organization to analyze the existing research to determine the diseases that are reasonably associated with damage to or suppression of the human immune system resulting from herbicide exposure.

We also favor the establishment of a mechanism for presumption of these diseases, as called for in S. 1787. Although it is not scheduled for consideration today, I must express The American Legion's support for another bill, S. 1805, which would exclude payments made to veterans or their survivors under the Agent Orange Liability Settlement Fund from being counted as income for pension purposes.

We would recommend that this exclusion of income be extended beyond Veterans' Administration programs to include any need-based Government assistance program.

Mr. Chairman, The American Legion is deeply troubled by what has been discussed earlier today, and that is the Centers for Disease Control's conclusion that the Agency cannot find enough data on veterans who were exposed to Agent Orange to do a scientifically valid study of its effects.

After a series of major administrative and methodological problems forced the study to a standstill, and then CDC conducted a pilot study of its own design, it was no great surprise to us that they concluded that the study could not be done.

We voiced concern about the composition of the study population almost 2 years ago. Thousands of veterans were eliminated based on criteria set down by CDC, many of whom no doubt were heavily exposed to Agent Orange. In fact, it is reported that 83 percent of the original study subjects were disqualified based upon that criteria.

The United States sprayed more than 12 million gallons of Agent Orange over a country that is smaller than the State of New Jersey. We feel it is absurd for CDC officials to state that they cannot find enough people to study.

It is unfortunate that CDC was permitted to develop a study that was destined to fail.

Finally, in closing our summary, given the emotional climate in which this entire matter has been considered, it would be well, we feel, for the Federal Government to lean in the direction of liberality while the scientific questions are still being considered.

Mr. Chairman, that concludes our summary.

Chairman CRANSTON. Thank you very much. Mr. Gorman?

[The prepared statement of Mr. Sommer appears on p. 315.]

STATEMENT OF DAVID W. GORMAN, ASSISTANT NATIONAL LEGISLATIVE DIRECTOR FOR MEDICAL AFFAIRS, DISABLED AMERICAN VETERANS

Mr. GORMAN. Thank you, Mr. Chairman. On behalf of the more than 1.1 million members of the Disabled American Veterans—of which approximately 400,000 are Vietnam veterans—may I say how very much we appreciate the opportunity to be here today. Also, Mr. Chairman, you have our sincere appreciation for the timely conduct of these hearings on this most important matter.

As you are aware, the Centers for Disease Control, which has been mandated to conduct the most comprehensive study to date of the health effects of Agent Orange, terminated during September of 1987 their contracts under which they had planned to conduct the study.

That action effectively, as we understand it, cancelled the CDC Agent Orange Study mandated by Public Law 96-151.

Mr. Chairman, CDC's action was apparently predicated upon their determination that it was not then possible to identify a large enough number of exposed veterans based on military records alone, upon which to base a large-scale study.

Frankly, Mr. Chairman, we view CDC's decision to totally abort that study incredulous and simply an acknowledgement that their preferred method of conducting such research was not felt feasible at that time.

Mr. Chairman, it has been over 20 years since the initial spraying of Agent Orange occurred in Vietnam. Since that time, untold thousands of veterans, as well as their families, have been fearful, confused, frustrated, uninformed, and extremely patient while waiting for answers to be found or for action to occur on this issue.

They still wait patiently. They still wait for their Government to acknowledge various maladies as possibly being a related or unrelated result of their military service and exposure. Further, they wait for some degree of assurance that the Government is really doing something to address those concerns in an honest and meaningful fashion.

Many veterans feel this is not currently occurring.

Clearly, to expect veterans to continue to wait until a large-scale epidemiological study and associated long-term research is completed is not now a realistic response.

Mr. Chairman, with respect to the pending legislation, the DAV wishes to acknowledge Senator Murkowski for his efforts in the construction and introduction of S. 1692. The DAV supports that portion of this legislation that would provide presumptive service connection for non-Hodgkin's lymphoma.

In our view, a sufficient body of scientific and medical evidence currently exists that adequately supports this measure.

Mr. Chairman, we would like to also take this opportunity to acknowledge and thank Senator Daschle for his continued interest and support for Vietnam veterans as evidenced by his introduction of S. 1787. The DAV supports that portion of S. 1787 which would extend service connection on a presumptive basis for non-Hodgkin's lymphoma.

However, we are unable to support sections 3(b) or 3(c) of the legislation or that portion of it dealing with presumptive service connection for lung cancer or involvement of the immune system. With respect to section 4 of the bill, we have no objection to implementing a procedure that would require the VA to seek a mechanism attempting to identify and determine, based on available scientific literature, specific disabilities that are reasonably associated with exposure to Agent Orange.

We would offer a cautionary note, however, that the organization charged with this responsibility not proceed in a passive manner or be duplicative of similar ongoing studies and efforts.

Also, we do not feel it wise to require the Administrator of the Veterans' Administration to accept such a list and implement regulations to grant service connection for such disabilities. We believe that discretion should be conveyed to the Administrator with appropriate congressional input to determine exactly what disabilities may be included in those regulations.

Finally, Mr. Chairman, we agree with the intent of section 5 of the bill. It is our belief that an exercise of compiling and analyzing the examination and treatment results of certain veterans may prove to be beneficial and assist in the research for solutions to this issue.

Thank you very much, Mr. Chairman.

Chairman CRANSTON. Thank you very much. Mr. Bollinger?

[The prepared statement of Mr. Gorman appears on p. 325.]

STATEMENT OF JOHN C. BOLLINGER, ASSOCIATE LEGISLATIVE DIRECTOR, PARALYZED VETERANS OF AMERICA

Mr. BOLLINGER. Thank you, Mr. Chairman. I am John Bollinger from PVA, and it is a privilege for me to be here today. I am going to present the views of PVA in regard to the status of studies reviewing the potential health effects within the Vietnam veteran population following exposure to herbicides.

We appreciate the opportunity to comment specifically on legislation S. 1692, introduced by Senator Murkowski, and S. 1787, introduced by Senators Daschle and Kerry.

The search for clues to discover the effects of Agent Orange had been long and difficult. At times, the science hasn't been perfect, and many times the full commitment to pursue that science hasn't been complete. But we are still much farther down that road than we were 5 or 10 years ago.

We would like to commend Senator Murkowski and Senator Daschle and Senator Kerry for their deep concern in introducing the legislation before us today. Both bills keep the attention of Congress on this important concern, which we believe to be proper.

However, PVA does not believe that a connection can currently be found and firmly established between exposure to Agent Orange in Vietnam with disabilities that can be extrapolated to the entire Vietnam veteran population based on the scientific evidence that we have reviewed to date.

The presumptions for disability compensation called for in both bills, non-Hodgkin's lymphoma and lung cancer, are drawn from only the partial results of the VA's study entitled "Proportionate

Mortality Study of Army and Marine Corps Veterans of the Vietnam War."

The presumption for disability compensation for certain immunosuppressant diseases contained in S. 1787 was not based on attributable findings of mortality appearing in the recent VA study of veterans, but is drawn from other studies, including studies on non-Vietnam veterans which has suggested a link between persistent exposure to dioxin and these diseases.

Taking both Army and Marine Corps Vietnam veterans as a group and comparing them with equivalent veterans who did not serve in Vietnam, there appears to be no major difference in the mortality experience in either veteran cohort.

We believe that in breaking the main study group down, the statistical credibility of the entire study is greatly weakened. Attempting to transfer statistical fact from a subgroup—in this case, the Marine Corps Vietnam veterans—to imply general liability for incidence of a disease within the study group as a whole does not make a good case, in our opinion. Yet, the bills before us today would do just that.

The bills would provide a presumption for service-connected disability for NHL and lung cancer for the entire Vietnam veteran population based on the findings tabulated only for the Marine Corps Vietnam veterans.

This would be done regardless of the fact that the study did not review the mortality experience of the Air Force, Navy, and other in-country Armed Forces personnel, or that the Army Vietnam veterans who served in areas where they could have had potentially higher levels of exposure to Agent Orange exhibited none of the same statistical significant elevations in causes of mortality.

Perhaps this is the most consistently troubling aspect of attempting to solve the Agent Orange dilemma. Both bills would utilize the VA's definition to quantify veterans exposed to Agent Orange as "any veteran who performed active military, naval or air service in the Republic of Vietnam during the Vietnam era is considered exposed."

This definition admits the current failure of science or historical record to identify exactly who, of the 3 million men and women who served in Vietnam, were exposed to Agent Orange, when they were exposed, and how much dioxin they were exposed to.

There has been a common perception in recent years which cites Agent Orange—and Agent Orange alone—as the culprit responsible for a diverse and extensive list of unexplained disorders among Vietnam veterans. The legislation before us today does basically the same thing.

It calls for a presumption for compensation attributing illness to exposure to Agent Orange, and only Agent Orange, for certain disabilities, both common and rare, which could surface in the Vietnam veteran population at any time.

In PVA's opinion, the only way we can solve this puzzle is to treat Agent Orange as one among many potentially harmful experiences and elements to which Vietnam veterans were potentially exposed. If there are groupings of disabilities for which compensation is not now authorized which appear at statistically significant levels for the entire Vietnam veteran population, we should proceed to provide a mechanism to authorize that compensation.

By far, the vast majority of evidence to date has shown that Vietnam veterans as a group are not at higher risk to certain systemic diseases than those veterans who did not serve in Vietnam. While we would support any effort to provide compensation for Vietnam veterans if scientific evidence could confirm that that compensation was warranted, based on solid and corroborated scientific evidence, we would do so.

However, proceeding to provide that compensation on the basis that science failed us and that we might never be able to solve this puzzle seems unreasonable to us. That concludes my statement, Senator.

Chairman CRANSTON. Thank you very much. Mr. Thorson?

[The prepared statement of Mr. Bollinger appears on p. 338.]

STATEMENT OF GORDON R. THORSON, SPECIAL ASSISTANT, NATIONAL LEGISLATIVE SERVICE, VETERANS OF FOREIGN WARS OF THE UNITED STATES

Mr. THORSON. Mr. Chairman, thank you for scheduling this hearing and allowing the Veterans of Foreign Wars an opportunity to speak out on the Agent Orange issue.

The VFW does not pretend to have all the answers, but we do believe that there is a reasonable course of action. We recognize that much research and study is still necessary to fully understand the total effect dioxin has had on the human system.

We fully support continuing that research as research is vital to a complete understanding of the impact that dioxin and specifically 2,3,7,8-TCDD has had on our soldiers. However, these studies have already spanned 10 years and, of necessity, will continue far into the future.

It is time to take the information already accumulated and apply that knowledge toward an effective plan of action to help the individual veteran claimant.

Again, let the studies and research continue; but in the interim, action must be taken now to address the many Agent Orange disabilities claimed by thousands of this country's veterans. We suggest the straightforward approach as outlined in our written testimony.

To summarize that testimony, we ask Congress to write and pass legislation that would allow all presumptive disabilities that can logically be associated with dioxin—again, specifically 2,3,7,8-TCDD; provide veterans with the opportunity to undergo a blood plasma or an adipose tissue test—either of those tests would do—or both; establish a committee to survey existing and ongoing scientific data.

And also require the scientific committee to, first, determine the level of retained dioxin thought dangerous, whatever it might be, whether it be any small amount of dioxin or a large amount; second, that committee would also continually expand the list of presumptions as knowledge increases. In other words, each year, as medical knowledge expands, the list would expand or contract, as need be. Because we do not know everything there is to know about dioxin, the studies must continue; but we do know enough to establish a reasonable and fair procedure for perfecting, presenting, and establishing a claim for service-connected compensation. Based on the knowledge that: All in-country Vietnam veterans are already presumed by the Veterans' Administration to have been exposed to a herbicide containing dioxin. (That is stated specifically in 3.311(a), section B of the Code of Federal Regulations.)

Dioxin, specifically TCDD, is the toxin found in Agent Orange that has been most identified as the problem ingredient. And certain disabilities obviously can result from dioxin exposure.

Therefore, it is only reasonable to establish a list of dioxin-related presumptive disabilities; provide the blood plasma test or the adipose tissue test to help validate residual disability; and finally, allow all benefit of the doubt in favor of the veteran, thus allowing veterans a reasonable opportunity to establish service-connection disability with the Veterans' Administration.

To conclude, the VFW calls for reasonable, compassionate, and yet responsible action on this issue. Thank you.

Chairman CRANSTON. Thank you very much. Ms. Stout?

[The prepared statement of Mr. Thorson appears on p. 351.]

STATEMENT OF MARY R. STOUT, PRESIDENT, VIETNAM VETERANS OF AMERICA, INC., ACCOMPANIED BY DR. THOMAS A. GASIEWICZ, ASSOCIATE PROFESSOR OF TOXICOLOGY, DEPARTMENT OF BIOPHYSICS, UNIVERSITY OF ROCHESTER, ROCHESTER, NY

Ms. STOUT. Thank you, Mr. Chairman. It is a pleasure to be here to represent the Vietnam Veterans of America. I am here, as you are here and many others have been here, for the past 9 years, asking Congress to pass legislation to address the needs of Vietnam veterans who have illnesses associated with their exposure to Agent Orange in Vietnam.

The Vietnam Veterans of America strongly supports S. 1787 because we think this is the most appropriate, if somewhat modest attempt to assist these veterans, while continuing the search for more definitive answers as to the risks associated with exposure to dioxin.

The VA's release of the Proportionate Mortality Study last fall has given rise to the interest on the part of Congress to give compensation for non-Hodgkin's lymphoma and lung cancer. Quite honestly, we don't understand why the Veterans' Administration, based on their own study, has not moved forward to promulgate some rules for compensation for the veterans who have been shown to have lung cancer and non-Hodgkin's lymphoma.

We also don't understand why the Veterans' Administration has not bothered to collect the information about what illnesses those 1.1 or 4.1 million—depending on what report you read—veterans have contracted due to their exposure; but the VA has not bothered to collect that information.

One aspect of S. 1787 which we have not heard very much information about today is about the immunosuppressive aspects of dioxins. And to assist this committee in understanding this aspect, we have asked Dr. Thomas Gasiewicz, Associate Professor of Toxicology at the University of Rochester, to participate in our presentation today.

Professor Gasiewicz' primary professional interest is in the biochemical and molecular mechanisms of toxicity. The major focus of his research since 1977 has been on the toxicity of dioxin, and I appreciate your allowing him to join me today.

Chairman CRANSTON. Go right ahead.

Dr. GASIEWICZ. Thank you, Mr. Chairman.

Chairman CRANSTON. We appreciate your coming.

Dr. GASIEWICZ. One approach to determining the human health risk of dioxins is to identify the health effects elicited and determine the relationship between the specific exposure and incidence of the effect in human populations.

In the case of dioxins, it is clear that some toxic effects, such as chloracne, have been observed. Although other responses such as cancer and immune alterations have been suggested to be caused by dioxin, these have not been conclusively demonstrated in humans. However, given the limitations of these data from human studies, these are unlikely to be demonstrated in the near future, whether or not such effects really exist.

There may be many reasons for this, some of which you have heard already today; but probably the main limitation is a lack of data on the amount of exposure in humans. Therefore, most previous human studies are of limited use in determining any exposure-response relationship and do not rule out the possibility of adverse effects occurring in individuals of exposed populations.

Due to these limitations, it is scientifically sound, appropriate, and necessary that any human health risk assessment of dioxins consider the wealth of information available from animal studies.

From these animal data come consistent findings. First of all, dioxin is extremely toxic to all mammalian species yet examined. Second, among the consistent effects observed in mammalian species include those on the immune system. This system is one of the most sensitive to dioxin exposure, and it has been shown that certain human cells of the immune system are just as sensitive to dioxin as the same cell types from experimental animals.

Three, dioxin has been shown to be carcinogenic in a number of animal studies. Four, the molecular events by which dioxin alters gene expression, that is DNA expression, in human and animal cells is similar.

In summary, in light of the limited usefulness of human population studies, it is scientifically sound and necessary for a committee reviewing the potential human health risks of the dioxins to consider experimental animal studies and those conducted on human cells.

Due to the consistent nature of some of these studies, it is reasonable to deduce that similar toxic effects are likely to be seen in humans at some level of exposure.

I believe Ms. Stout has a closing statement.

Ms. STOUT. I will end our statement by reminding this committee that three major pieces of legislation have been passed to address the issue of Agent Orange.

The first mandated an Agent Orange study of Vietnam veterans. No such study has been done.

The second mandated health care, yet we have no way to assess what has been done in this area; and the VA has inflated figures or no data to reflect the illnesses for which veterans are receiving health care.

The third called for compensation. No Vietnam veteran we are aware of has received compensation for an Agent Orange related illness yet.

We call upon you to take the leadership on this issue, the leadership Senator Murkowski spoke of last September 17, when he said: "Leadership is a willingness to take action in the face of incomplete or imperfect data, rather than accepting a paralysis inherent in a never-ending wait for perfect understanding."

Thank you for this opportunity to present our views.

Chairman CRANSTON. Thank you very much.

[The prepared statements of Ms. Stout and Dr. Gasiewicz appear on pp. 360 and 386.]

Chairman CRANSTON. I would like to ask if each of you would give us in writing your reaction to the CDC Vietnam Experience Study.

Second, you heard testimony today from the VA on the proposal to establish within DM&S a new Environmental Medicine Office. I would like to ask each of you if you think that is a good idea. Do you support that concept?

Mr. GORMAN. Mr. Chairman, we haven't as yet seen any kind of proposal along that line, but I think of concern would be by taking all environmental hazardous issues and lumping them into a singular office may well create the perception that the VA is devoting less attention and placing a lower priority to the issue of Agent Orange. So, I would have to reserve my judgment for the time being.

Chairman CRANSTON. Any other comments?

Mr. SOMMER. Mr. Chairman, The American Legion would also like to see the proposal. However, if a sufficient amount of expertise and a sufficient amount of resources and a sufficient amount of staffing were given to an office like this, it may enhance the Veterans' Administration's ability to handle these types of very controversial issues.

Chairman CRANSTON. Any other comments?

Dr. GASIEWICZ. Mr. Chairman, comments have been requested from several witnesses regarding my report. I was wondering, Mr. Chairman, if I might receive those comments and get a chance to respond to the committee, to those comments?

Chairman CRANSTON. Yes.

Dr. GASIEWICZ. Thank you.

Chairman CRANSTON. Fine. Thank you very much. We appreciate your testimony.

We will now hear from our final panel, beginning with Ms. Judy Lewis and Ms. Mary Barton, National Association of Agent Orange Survivors; Mr. J. Thomas Burch, Jr., Chairman, National Coalition of Vietnam Veterans, accompanied by Mr. David F. Carter, Chairman of the Oklahoma Agent Orange Foundation; Major Jack Spey, U.S. Air Force, Retired, President, Ranch Hand Vietnam Association; Mr. Wayne P. Wilson, Executive Committee Member, National Association of State Agent Orange Programs; Mr. Frank McCarthy, President, Vietnam Veterans Agent Orange Victims, Stamford, CT; and Mr. Christopher Gregory, a Massachusetts Vietnam veteran.

I thank you all for your patience through this long hearing. I know of your deep interest. Ms. Lewis, would you please begin?

I want to explain that I will have to leave for a few moments, but I will be back shortly. Please proceed with your statement, Ms. Lewis.

STATEMENT OF JUDY C. LEWIS, NATIONAL COORDINATOR, NATIONAL ASSOCIATION OF AGENT ORANGE SURVIVORS, OAKS, PA, ACCOMPANIED BY MARY BARTON, NATIONAL FUNDRAISING DIRECTOR

Ms. Lewis. Mr. Chairman, thank you. We were invited to give our opinion on S. 1692 and S. 1787. We are in favor of any legislation which would aid veterans. We have learned over the past several days that legislation already exists which would compensate the veterans, which is being ignored, and passage of S. 1692 or S. 1787 may only further complicate the issue and provide additional loopholes for the Veterans' Administration.

We believe that the current legislation should be in force and Vietnam veterans compensated now. Since 20 percent of all Vietnam veterans are now deceased, perhaps the Government is waiting for all these veterans to die; and in that way, there will be no need to resolve this issue.

In the limited time I am allotted today, I would like to share some of the information we received at a conference held on May 9. This conference was supported by, among others, Senator Thomas Daschle, who I understand was in attendance earlier, in a speech at the conference.

In the speech, reference was made to a conspiracy. I would like to say at this point that there is a gentleman, the only living Vietnam veteran, being compensated for exposure to Agent Orange in Australia who can prove that a conspiracy did take place. I would be happy to discuss this further after the hearings.

I will now, with your permission, read portions of the opening speech from the International Agent Orange Conference.

The comments reflect an issue of recent history that is the use of contaminated herbicides, most notably during the Vietnam war and in areas of the United States, now considered uninhabitable by many experts.

We will—about Agent Orange and will present evidence that Vietnam is but another chapter in an ongoing conspiracy, using American military and the civilian population for research and development of carcinogens. We will trace activities of the Federal Government and the military establishment in testing biological and chemical substances indicative of a conspiracy that remains——

This conspiracy can be traced back over three decades. We will introduce evidence that, through—tests, the many factors of these herbicides have had—since 1948, but continued production of these herbicides until 1983. This continuing production, when it became obvious that continued production could result in the release of potentially damaging evidence of the toxicity of their products.

We will introduce evidence showing that the Government and the military continued using dioxin and contaminated herbicides long after public health concerns had become apparent and that those citizens of South Vietnam and citizens of South Vietnam under Viet Cong control may have been warned of the highly toxic nature of these herbicides while no precautions were taken for U.S. personnel.

The drums used to store were only—some of these drums were later used to hold water for showers and as barbecue pits. There were no warnings on these drums of the possible harmful effect.

We will also introduce evidence to show that the U.S. Government's military personnel used the—and the country of Vietnam as a laboratory. In cooperation with Canada and the United Kingdom to conduct chemical and biological warfare experiments of living and fighting in a toxic environment in a selected part of the country.

This research was but a continuation of testing of biological and chemical agents that included spraying of populated areas of the United States. In total—experience in the United States are 239 cases. This does not include testing of the—soldiers used to test biological and chemical substances.

This information I have been reading from does have documentation to support it; and I just wanted to report it. Our veterans are very concerned that the Government would have a part in doing something like this.

Chairman CRANSTON. Thank you very much. Please submit your whole statement and any documents you may have for the record.

Ms. Barton.

Ms. BARTON. All right. Thank you for inviting me here today. I am proud to be here today representing thousands and thousands of Vietnam veterans and also thousands of Vietnam veterans' wives and widows.

I urge that some measures be taken so that we can eventually test the dioxin level in these veterans because as one veteran—my husband—was tested—and I understand Dr. Hopsen stated this was an error, a mistake; he should never have been tested—and I don't have an answer to that, as to why to my knowledge he is the only Vietnam veteran that has been tested recently. I would like to have an answer to that.

Again, thank you for inviting me here today.

Chairman CRANSTON. Thank you very much.

Mr. Burch.

[The prepared statements of Ms. Lewis, Ms. Barton, and Mr. Reed appear on p. 390.]

STATEMENT OF J. THOMAS BURCH, JR., CHAIRMAN, NATIONAL VIETNAM VETERANS COALITION, ACCOMPANIED BY DAVID F. CARTER, CHAIRMAN, OKLAHOMA AGENT ORANGE FOUNDATION

Mr. BURCH. Mr. Chairman, I am Tom Burch, Chairman of the National Vietnam Veterans Coalition. First, I would like to thank you, Mr. Chairman, for the leadership you have shown in giving the Vietnam veterans of this country an opportunity to present views before this committee. It is your leadership that has enabled us to do that.

The National Vietnam Veterans Coalition is a federation of 45 independent Vietnam veterans' organizations. It includes all but one of the major independent groups. Among the groups in the coalition that are primarily interested in Agent Orange that we are spokesmen for today are the Colorado Agent Orange/Atomic Radiation Coalition, the Oklahoma Agent Orange Foundation, Veterans of the Vietnam War, Inc., Vietman Veterans Agent Orange Committee, and Vietnam Veterans Agent Orange Victims, Inc.

We would like to make it very clear, Mr. Chairman, that we as Vietnam veterans feel it is time that the Congress took decisive, meaningful action on Agent Orange. We unequivocally endorse S. 1787 and ask this committee to enact that legislation and pass it onto the Senate for passage by this Congress.

To conclude our remarks on behalf of the coalition, I will call on the Chairman of the Oklahoma Agent Orange Foundation to give more definitive remarks.

Mr. Carter.

Mr. CARTER. Thank you, sir. The VA must be mandated to provide specific health care for specific diseases. Why? Because a conflict of interest has arisen in the VA structure. If proper medical care is given to veterans suffering from the effects of chemical warfare weapons, then that admission of a problem backs veterans' disability claims, which cannot be granted because of budgetary restraints.

At the same time, U.S. defense contractors are pressuring for more so-called "conclusive" evidence of damage to American veterans by their products, because those unsafe products have been sold for general use since the U.S. Government's wise decision to halt their use in Vietnam.

What this amounts to is that benefit of doubt given to veterans by the U.S. Code of Military Justice has instead been given to a chemical, rather than a citizen. The truth is that these chemicals are carcinogenic and are cancer promoters. They cause chromosome damage, are teratogenic, mutagenic; they damage the thyroid, kidneys, heart, and blood-forming organs, liver and brain.

They may be the main cause of autoimmune diseases such as rheumatoid arthritis, mixed connective tissue disease, and systemic lupus erythematosus. They cause changes in mood and promote antisocial behavior.

They are excreted in seminal fluid and, as such, are not only sexually transmitted to our wives, but they also expose the fetus in the uterus. They damage and/or compromise the human immune system, and they are in fact at least a cofactor and more probably the direct cause of the expression of leukemia viruses; and that would include the so-called "AIDS epidemic."

And the children of exposed parents are predisposed to leukemias.

Because of the fact that the VA hospitals are intricate parts of many teaching hospitals, the Veterans' Administration disinformation filters to medical students, who are then faced with the tasks of treating American civilians suffering from chemically induced illnesses, not only with little training in the field, but they must face this task after being diseducated.

For instance, the VA altered literature to remove a cancer warning issued to Vietnam veterans and their physicians; hence, thousands of exposed veterans and civilians have been denied the benefit of early detection for certain cancers.

Also, medicines that our physicians use sometimes actually worsen the symptoms of a misunderstood disease, for instance cortisone. And a recent CDC Vietnam Experience Study was released in two versions—one version in an inaccurate article in the Journal of the American Medical Association that goes to your children's doctors, and a more correct article in the CDC monograph with less than adequate distribution.

There are many parallels between the war technologies of radiation and toxic chemicals. Perhaps most noteworthy is the brain damage suffered by our children. Eighteen years after every aboveground nuclear test in Nevada, the SAT scores of the U.S. children fell.

Much information is available on actual physical brain damage occurring because of toxic exposure, yet many hundreds of 55 gallon drums of military surplus Agent Blue was used as a contact herbicide in our public schools; after its use was discontinued in Vietnam; and as of yet, there have been no health warnings issued. War technologies do not make good peacetime businesses.

I recently made a presentation to high school seniors; they immediately saw the folly of Americans slaughtering Americans for profit. We must correct this situation openly and honorably if we are to encourage the next generation to preserve this Republic. They are watching.

A couple of quick statements on what I have heard today.

You representatives of we, the people, must pay attention to the synergistic effects of multichemical exposure and not just the narrow issue of Agent Orange.

There is no normal of a synthetic chemical in a human being. The fact that there is an average is our shame, but there is no normal; and you must remember individual tolerances.

And remember that veterans were a healthier group of citizens before they were in the service. So, even if our health has deteriorated to the point of being average, that is in fact, a decline.

In conclusion, we will call for the immediate support of S. 1787, and we hope this results in direct health care for Vietnam veterans. Thank you very much for your time.

Mr. BURCH. Thank you, Mr. Chairman.

Chairman CRANSTON. Thank you very much. We will have to have a brief recess, and then I will hear the rest of your statements.

[The prepared statement of Mr. Carter appears on p. 429.]

Chairman CRANSTON. We will proceed now and hear from Maj. Jack Spey.

STATEMENT OF MAJ. JACK SPEY, U.S. AIR FORCE (RET.), PRESIDENT, RANCH HAND VIETNAM ASSOCIATION, FORT WALTON BEACH, FL

Major Spey. Thank you, Mr. Chairman. My name is Maj. Jack Spey, U.S. Air Force, Retired. I served for 6½ years in Southeast Asia, 3 years in Laos with the Lao Air Force and 3½ years in Operation Ranch Hand.

Following that period, I spent 4 years training Ranch Hand pilots for their mission in Vietnam. I am currently President of the Ranch Hand Vietnam Association.

For almost a decade during the Vietnam conflict, 1,265 Americans served in the unique U.S. Air Force organization conducting a very unusual mission. The organization given the mission of spraying herbicides was known as Operation Ranch Hand.

For 9 years, 11.5 million gallons of agricultural herbicides were sprayed by Operation Ranch Hand. By all accounts, the mission was a military success. Analysts have stated that the herbicide program saved approximately 50,000 casualties.

By his own admission, the additional burden placed on the enemy's logistical system as a result of crop destruction slowed his advances. The increased vertical visibility resulting from the spraying of agricultural herbicide exposed the enemy's supply network and hampered his military objective.

The Ranch Hand mission was conducted in less than ideal conditions. The C123, a twin engine cargo aircraft modified for aerial spray applications, was flown at 150 feet above the terrain at 150 miles an hour. As a result of that altitude, the aircraft received over 7,000 rounds of enemy ground fire during its 9 year history.

One aircraft nicknamed "Patches" was hit by enemy ground fire over 800 times, and that aircraft is now on display at the Air Force Museum at the Wright-Patterson Air Force Base.

The outstanding performance and bravery of the personnel of Operation Ranch Hand was appropriately recognized by our Nation. The organization was awarded five Air Force Outstanding Unit Awards on two occasions with the "V" device for valor and received two Presidential Unit Citations, in addition to receiving the Vietnamese Cross of Gallantry by the Vietnamese Government on two occasions.

Since 1975, the American public has been bombarded with inflated press accounts highlighting emotional claims made by a very few people. This has led to the perception that Operation Ranch Hand doused the Vietnam countryside with the dioxin, dousing or drenching those people on the ground, either combatants or noncombatants. And this is simply a myth.

Our aircraft sprayed at the rate of 3 gallons per acre, which is the equivalent of nine-thousandths of an ounce per square foot. We are generally familiar with a whisky shot glass. If I divided this glass into 1,000 parts and filled 9 of those parts and turned it up over my head, which is less than a 1 square foot area, that is certainly not a "dousing."

It is true that the herbicide Agent Orange contained dioxin as a result of production. The amounts ranged on the average of 2 parts per million, or the equivalent of 2 inches in 200 miles.

Dioxin was not a component of the herbicide 2,4-D or 2,4,5-T. It was not a major element, nor was it an ingredient, as has been characterized by the press. It was a contaminant and a contaminant degradable by sunlight.

The men of Operation Ranch Hand had but one mission in Vietnam, the herbicide mission; and our contact with those chemicals was daily. The crew were in contact with them from preflight of the aircraft until the aircraft landed.

Maintenance personnel were in daily contact with these aircraft, as they repaired continual battle damage and the spray equipment. Our contact was not casual; it was an integral part of our work during our service in Southeast Asia.

The bottom line in this whole Agent Orange controversy is the human health 2,4-D/2,4,5-T question. Does 2,4-D/2,4,5-T harm people? It is a scientific question requiring a scientific approach for resolution.

The vast quantity of scientific literature dealing with 2,4-D/2,4,5-T supports the contention that it is a safe herbicide when that information is examined as a whole.

For the past 8 years, the Air Force Health Study, a hallmark scientific effort by this Nation, has been examining the mortality and morbidity of the American service personnel who experienced the greatest degree and frequency of physical contact with herbicides during the Vietnam conflict.

Thus far, the conclusions of this ongoing study show no significant differences between Ranch Hand personnel and the comparison group.

Did the mission of Operation Ranch Hand do harm to those who performed it? Or did it do harm to those combatants or noncombatants who may have been on the ground?

Chairman CRANSTON. Major, I am sorry, but you are out of time; and I have to go vote in a minute.

Major SPEY. When the facts and science are weighed in total, the answer remains no. Thank you, Mr. Chairman.

Chairman CRANSTON. Your full statement will appear in the record.

[The prepared statement of Major Spey appears on p. 447.]

Chairman CRANSTON. I would like to say to the last witnesses that, if you can express your thoughts to me briefly, in about a minute and a half, I will hear them. Otherwise, I have to go and vote; and I cannot come back because I have another commitment. So, may I ask you to express whatever you feel in a few moments?

STATEMENT OF WAYNE P. WILSON, EXECUTIVE COMMITTEE MEMBER, NATIONAL ASSOCIATION OF STATE AGENT ORANGE PROGRAMS

Mr. WILSON. Senator, I have sat here today and I have heard a lot of statistics batted around, and I have heard Major Spey state the shot glass analogy. I think for those Vietnam veterans who cannot be here today, they would be pretty much appalled at what is going on.

I am a State official, and I am representing my colleagues from around the country; and I am not going to pull any punches. I think that we are unhappy in many respects with what the Federal Government is doing. We are unhappy with what they are not doing.

Quite candidly, I heard Mr. Harvey's comments this morning; and I think the Vietnam veterans themselves will tell you that the care and treatment that they so need is just not there.

For my colleagues, I will say we endorse S. 1787, and I think it is just time to get on with this. For me to come back here, or for any of us to come back here, in 5 or 10 years to continue this debate does not serve Vietnam veterans and their families.

Chairman CRANSTON. Thank you for expressing that so directly and so candidly. Mr. McCarthy?

[The prepared statement of Mr. Wilson appears on p. 450.]

STATEMENT OF FRANK McCARTHY, PRESIDENT, VIETNAM VETERANS AGENT ORANGE VICTIMS, INC., STAMFORD, CT

Mr. MCCARTHY. I will try to summarize in a minute and a half, Senator. I am very saddened that my colleague over there is gone for the day, Senator Simpson. The things that he said today were quite startling.

In our litigation against the chemical companies, we have 249,000 claims. We have 64,000 children born with birth defects as claimants. These are bona fide claimants. This is the issue.

I came here very enthused today. I haven't been around the circuit in a while. Our organization has been providing one-on-one services for the families affected. We are the only group in America that raises funds for the children born with birth defects whose fathers were exposed to Agent Orange.

We try to raise the funds to give these children an eyelid or an ear or a jaw, simply because the families don't have the money; and the insurance companies will not insure that.

So, my battle is to get funds for little children, to give them an eyelid, to give them an ear, to give them a jaw.

For a decade, Senator, this Government has debated the issue and spent $100 million. I submit to everyone in this country that, if that $100 million was spent on those children, I would be out of business. Please, Senator, go.

Chairman CRANSTON. I have 1 more minute. Mr. Gregory, if you can be very explicit, there will be time.

[The prepared statement of Mr. McCarthy appears on p. 456.]

STATEMENT OF CHRISTOPHER GREGORY, A VIETNAM VETERAN FROM THE STATE OF MASSACHUSETTS

Mr. GREGORY. Thank you very much. I will try to be as brief as I can. I came with a prepared statement, which I will leave.

I think you face generally a very difficult situation. This is not really a scientific question that is being discussed. It has largely become, because of the efforts of the VA, a political question.

I have found a lot of difficulty in the way they relate to independent studies and studies that take place in academia. They have willfully, I believe, obstructed studies that we have attempted and completed in the Commonwealth of Massachusetts.

Three of them I have with me today. They have passed peer review, and they are in the literature.

I have also found a conflict of interest on the VA's Environmental Hazards Board, which I will submit to your staff.

It is a very difficult situation because the discipline and the distance from this question doesn't exist, and I don't think can exist from a Government agency. It is an unfortunate thing.

I support this legislation. I think it should be passed. I think other diseases should be included, and I would hope that it would lessen the suffering of some of the many veterans whom I see.

Chairman **CRANSTON**. I want to thank you very much. I want to particularly thank this panel for your concerns and your patience. I know how deeply you feel about this. I am sorry I didn't have more time with you. I wanted to hear more, but I know that your full statements will be in the record.

We did have to get the scientific basis from the experts and so forth who were here, before hearing your views on this. Jon Steinberg, the committee counsel, does have some questions to ask. I will have to leave and be unable to return, but he will complete this hearing.

Thank you all very, very much.

[The prepared statement of Mr. Gregory and related studies appear on p. 479.]

Mr. **STEINBERG**. First, I would like to offer to Mr. McCarthy and Mr. Gregory and Mr. Wilson the 3½ minutes that your testimony was curtailed by. So, if you would like to put into the record any additional statements at this time, we will start with Mr. Wilson; and you have 3½ more minutes. Then, we will have a couple of questions.

It is entirely up to you. If you wish to yield that time back, that is acceptable also.

Mr. **WILSON**. I think I won't give it back and I won't finish my prepared statement, but I think I would just like to address a couple questions. I said a few moments ago that many of my colleagues around the country have been very critical of the Veterans' Administration and very critical of the Federal Government on this issue.

I note that considerable time was spent today examining and discussing with CDC and the Air Force and other Government agencies their role and what they have done—and perhaps what they haven't done—and I would suggest that, if we are going to go on with this business any longer—and I hope we don't—that perhaps you might expand the list of people to come in and perhaps offset some of the things that have been said by the Government.

One of the men in the back passed me a note that indicated that Ms. Gelband of OTA had indicated how dioxin broke down in the environment. And yet, as I sit here today, I am aware of some work done with our State Commission in New Jersey on the Vietnamese that indicates—and recent work that has not yet been published—that a study showing that dioxin has spread beyond the environment that Major Spey talks about having sprayed in Vietnam.

And they are now finding levels in people who were not even in the southern part of the country during those war years. So, I think there are some serious questions here, and we can debate these for any number of years, I would suggest.

But I think that what we are here for today is that I will tell you that there are tens of thousands of Vietnam veterans out there who are sick. There are widows and there are families; and my greatest fear is this: Suppose all of us experts are wrong? Suppose they discover the dioxin was the problem?

And when Vietnam veterans ask for our help—we spent years debating it up here on the Hill—or we deny them; and we will really have made a mistake. It is a presumptive legislative bill; I think we ought to go ahead and move with it and respond to the families and veterans who need help now—not 5 years from now.

To them, it is not a question of who is right or who is wrong. They ask for help now; they should have it. They deserve no more, but they certainly don't deserve any less.

I will tell you this. I think the Vietnam veteran out there in the real world will tell you that they are getting short shrift on this issue from the Veterans' Administration and from the Federal Government, and in their hour of need.

Quite frankly, I am not sure I will come back up here to debate this next year and the following year. I think it is an insult to Vietnam veterans and their families to keep doing this.

With that, I will conclude my statement.

Mr. STEINBERG. Thank you, Mr. Wilson. Mr. McCarthy, would you like 3½ minutes?

Mr. MCCARTHY. Yes. I would like to have a little more time to talk about children.

To pick up where I left off, we have 64,000 claims for children. Now, these families don't care whether Agent Orange caused the problem or not; and I think that this country has a moral and ethical responsibility to those children to legislate some kind of bill that will provide the care that they need.

What I am speaking directly of: If the political factions of the left and the right are going to continue to fight and reach an impasse, which is what has been happening for the last decade, and only deal in terms of compensation, the families are never going to get help.

We have 249,000 claims and 64,000 of our children with birth defects. Science, to us and to them, is never going to be able to conclude one way or another that Agent Orange caused that problem. It doesn't matter to us as human beings whether Agent Orange caused the birth defects of these children, if they are in fact reversible, if doctors can give them artificial eyelids or an artificial ear or an artificial jaw, and artificial teeth for these children.

We are denying them because the science can't tell us that Agent Orange caused the problem; then where are we as a society? Where are we as a society to look these children in the eye and say you have to look deformed all your life just because we won't commit the money to pay for the medical operation.

That is what we do every day in our organization, and it is heartbreaking to see these children. It is heartbreaking to look at the parents and say: We don't have the money for you today; maybe we will have the money for you tomorrow. Maybe some corporation will give us a lot of money.

Our $180 million settlement is up to $250 million right now. And contrary to what the Assistant Administrator of the Veterans' Administration gave out—terrible information about it—the lawyers are not getting a major bulk. That is not what it is about. Judge Weinstein has created a board of 11 veteran advisors, and we are determining how this money is to be spent.

Disability and death benefits amounting to $200 million will be spent on 12,500 families. The remaining $45 million is yet to be determined. Our organization is submitting a proposal that that $45 million be used for the children—where it should be.

But it is not the lawsuit's responsibility, and it is not the American public's responsibility, and it is certainly not the veterans' groups' responsibility; it is the Federal Government's responsibility to pay for these birth defects.

If they are reversible, why are we not paying for them? Only because all these scientists who come here and say: No; yes, it could be, no, it couldn't be. We have heard that for a decade now. How about helping the children? How about helping the families?

Why is the VA not getting out anticancer information? Why are we, the pathetically, inept financial organization, having to raise nickels and dimes to get out anticancer information?

A veteran called us and said he read the testicular cancer guide, called his doctor who found a tumor; and it saved his life. Thank you. Why are we doing this? Why isn't the Veterans' Administration doing that? They are hung up on politics or hung up on causal relationships or hung up on science.

We, as the victims, don't care whether Agent Orange caused the problem. To us the problem is no longer Agent Orange; it is the Federal Government because you are the problem. You are the ones who are hung up on politics.

We are left with the problems. We are left with our veterans and we are trying to deal with thousands of children; and we don't have the funds. Thank you.

Mr. **Steinberg**. Mr. Gregory?

Mr. **Gregory**. Yes, thank you. I would like to just briefly try to summarize what I was going to say earlier.

I would like to talk about three studies that have been conducted in Massachusetts and the results of those studies; but first, I think it is important that I talk a little about this conflict of interest that I have found.

Dr. Theodore Colton, who is a member of the Veterans' Advisory Committee on Environmental Hazards, is a prominent academic in our area; and he served on the Advisory Committee and was, at the same time, a paid advisor to a law firm representing Monsanto Corp. in a legal action brought by chemical workers who had been exposed to dioxin in Nitro, WV.

Frederic Conway, Executive Member of the Scientific Council, acknowledged these facts in correspondence with me in 1985, in answer to my letter informing him of Dr. Colton's apparent conflict.

Mr. Conway wrote to assure me that Dr. Colton's position was fully understood and that his situation was discussed with the present and former General Counsel of the Veterans' Administration and with the Agency's ethics official. And they, after due consideration, found no conflict of interest.

I find it hard to agree with their decision in light of the fact that Dr. Colton was on the payroll of Monsanto while he was involved in promulgating regulations to compensate injuries caused by exposure to Agent Orange, a Monsanto product.

It seems to me clear that Dr. Colton is indeed involved in a conflict of interest and that the regulations he helped to formulate are tainted as a result.

In my State, we tried to look at three different problems that we believe may have been related to the Vietnam experience. One is mortality, as a result of soft tissue sarcoma; and there were incidents of soft tissue sarcoma among Vietnam veterans as opposed to Vietnam era veterans not in Vietnam; and take a look at possible relationship between post-traumatic-stress disorder and exposure to Agent Orange.

We have done other research as well, but in these three cases, we managed to find fairly substantial connections, statistical connections in the case of the sarcomas and connections of other types of fairly solid connections having to do with PTSD. In all three of these research efforts, the Veterans' Administration could be characterized as at least uncooperative.

They declined to give us any information about chloracne. We found they recognized no cases of chloracne in New England. We were able to locate 42 cases of likely chloracne and active 6 cases. Chloracne is one certain medical indicator of dioxin intoxication, and should be studied by the VA, as opposed to being protected from public scrutiny by the VA.

The question that these results are leading to, although they are significant studies in their own right, is: How can we in Massachusetts, with a relatively small amount of money, find some very specific problems—statistical problems—that hold up in a body of science?

And the VA, which has put such vast amounts of money into research, has been unable to find anything? I think that is a very good question, and it is a question that I haven't heard asked today.

I and a lot of other veterans would appreciate it if, at some point, it was addressed and answered. Thank you.

Mr. **Steinberg**. Thank you, Mr. Gregory. We will certainly be glad to pose that question to the Veterans' Administration for this record. Let me ask each of you—and you can go in the order in which you testified, starting with Ms. Lewis—if you have any comments that you would like to make on the results of the Vietnam Experience Study that were released by the Centers for Disease Control this morning.

Ms. **Lewis**. No, I have no comments.

Mr. **Steinberg**. Mr. Burch?

Mr. **Burch**. I have one other comment before the conclusion of this hearing, and I hope you would let me make that. First, Mr. Carter?

Mr. **Carter**. The CDC Vietnam Experience Study was released in two forms, and I think if you look at the forms that are for public consumption and the forms that are for consumption by their peers, you would be in for a big surprise. And I would suggest that this committee do that.

Mr. STEINBERG. Thank you. Mr. Burch?

Mr. BURCH. If I could, this has been alluded to more in The American Legion's testimony, but it is a serious problem. The Veterans' Administration failed to implement the law that we fought so hard about 5 years ago to pass—Mr. Principi and different people, and Senator Cranston fought for that bill—it was only a $5 million bill.

Now, the VA, even though I have a 45-member group, they won't even meet with me to talk about implementation and the problems of Agent Orange. They refuse to even meet with us, and I think it is a disgrace.

The Veterans' Administration is supposed to be the advocate of the veterans, and they put themselves in an adversary relationship. We can't even talk about it because the VA Administrator refuses to meet with us about it.

Mr. STEINBERG. Major Spey, do you have any comments that you wish to make with respect to the study?

Major Spey. Can I do that in 30 seconds?

Mr. STEINBERG. Yes, sir.

Major Spey. I have to catch a plane at 6 o'clock, and I am not familiar with the geography around the Washington area.

Mr. STEINBERG. You are not going to have any problems getting there by 6 o'clock.

Major SPEY. One of the other myths about the herbicide program in Vietnam was the fact that a lot of people perceived or believed that the Ranch Hand people simply weren't the right people to study. The scientists have since come up with a blood serum index; they test the blood for dioxin and they can detect parts per quadrillion or something like that.

And a mathematician said 1 part per quadrillion is equivalent to stacking dimes from here to the sun and removing 1 dime. I have to accept his numbers.

There is no question, I don't believe, in anyone's mind that the Ranch Hand personnel had the greatest degree and frequency of contact. The pilot program for blood serum analysis shows that our blood level in dioxin on the mean average is about 55 parts per trillion, and the average person walking around the street in the city of Washington is anywhere from 8 to 11, depending on whose figure and whose laboratory you want to believe.

It is obvious the state is elevated, and it is elevated far in excess of those other individuals who served in Vietnam. That particular myth has been set aside in my mind, as a former service member serving in that mission for the length of the time that I did serve.

The other thing I would like to say in closing is that, as a very proud member of a very proud organization that remains so today, all of the science that I have heard today and the other science and facts that I have heard concerning this controversy over the past 15 years makes me feel very good.

It gives me reassurance. And I think when the facts and science are looked at and people take the time to simply look at it, they should take counsel in the facts and the science that have been presented on this issue up until now. Thank you, sir.

Mr. STEINBERG. Thank you very much. Mr. Wilson, did you have any comments you want to make on the Vietnam Experience Study?

Mr. WILSON. I have not had an opportunity to review it in any detail. I am not sure that it took 20 years for me to realize that Vietnam was not such a great experience, and I will let it go at that. And I wish Senator Simpson was here so I could show him my credentials. Thank you. [Laughter.]

Mr. STEINBERG. Mr. McCarthy?

Mr. MCCARTHY. I would like to comment on it. Logic demands that we were exposed to Agent Orange, Purple, Blue, White, carcinogenic pills, the myriad doses, various illnesses endemic to the Vietnam region, DDT, et cetera. I mean, the list goes on and on.

Yes, in fact, we have been injured by other factors in our Vietnam experience.

I would like to make sure that it is entered into the record that Judge Weinstein in the Agent Orange lawsuit has repeatedly asked the Government to enter in on the settlement. And he wasn't referring to that monetarily; he was referring to any way that the Government could be involved.

Now, the Justice Department was the only one that seemed to represent the entire U.S. Government. Now, the CDC is saying that they can't find properly exposed veterans; we have 249,000 claims.

Now, why can't the Government be involved with settlement in that they coordinate with Judge Weinstein and the Federal judiciary, and we will give them all the exposed veterans they need, bona fide, documented exposed veterans—and not just the Ranch Hands.

Another myth is that the Ranch Hand did the only spraying. Every base camp in Vietnam had its Agent Orange, and we sprayed our fields of fires, we backtracked, we trucked, tanked; we did it by every means available.

Everybody is just dealing with the Ranch Hand Association like that was the only application of the herbicide. In conjunction with that, coming back, we have been out of the service for 20 years.

Now, every great scientist that I have ever talked to around the world will tell you that it is illogical to assume that we are going to prove that it is Agent Orange after taking into consideration all that we have been exposed to and 20 years we have been exposed with what we deal with in the workplace, like every other American citizen, like every other human being working in this society.

So, yes, we smoke; yes, we drink; yes, we have psychological problems. Yes, we are, in fact, every segment of the American society. So, it is illogical for the Government to debate the issue of Agent Orange any further on a scientific basis. We have to deal with the human beings in terms of their suffering.

So, the CDC has to take that into consideration, too. They are not. It seems like the Justice Department is the only segment of the Government that represents the Government. Why can't the VA be involved, per se?

If we have a list of 249,000 veterans claiming damage, that is the cause; that is the issue. Those are the people. I can't speak for the Federal judiciary, but I am sure Judge Weinstein will do everything he can to help the Government because I know how he feels about the veterans. His main concern is to help them.

Mr. **Steinberg**. Mr. Gregory, do you have any comments on the study?

Mr. **Gregory**. I haven't really seen the study, only the newspaper article on it. I am not prepared to comment on it at this time.

Mr. **Steinberg**. We would be glad to have any written comments that any of you wish to make, after you have had more of an opportunity to look at that study. We do have some followup written questions for some of you.

Mr. Gregory, we are interested in your dealings with the Veterans' Administration in regard to your Massachusetts studies. So, we will be asking you some questions about that. And we have some questions for Mr. Wilson and for some others of you.

We appreciate very much your having remained with us. I believe Tony has no further questions. It is 2:40 p.m., and this hearing is adjourned.

[Whereupon, at 2:40 p.m., the hearing was adjourned.]

APPENDIX

II

100TH CONGRESS
1ST SESSION

S. 1692

To amend title 38, United States Code, to provide for the payment of a veterans' disability benefit in the case of certain veterans who have non-Hodgkin's lymphoma.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 17, 1987

Mr. MURKOWSKI introduced the following bill; which was read twice and referred to the Committee on Veterans' Affairs

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A BILL

To amend title 38, United States Code, to provide for the payment of a veterans' disability benefit in the case of certain veterans who have non-Hodgkin's lymphoma.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Agent Orange Disability Benefits Act of 1987".

SEC. 2. PRESUMPTION RELATING TO DISEASE OR DEATH RESULTING FROM NON-HODGKIN'S LYMPHOMA.

(a) PRESUMPTION OF SERVICE CONNECTION.—Section 312 of title 38, United States Code, is amended by adding at the end the following new subsection:

"(c)(1) For the purposes of section 310 of this title and subject to the provisions of section 313 of this title, in the case of any veteran who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era, the disease of non-Hodgkin's lymphoma shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of such service.

"(2) Paragraph (1) of this subsection shall not apply in the case of any claim received by the Veterans' Administration after September 30, 1991.".

(b) PRESUMPTION REBUTTABLE.—Section 313 of title 38, United States Code, is amended by adding at the end the following new subsection:

"(c) The presumption of service connection provided in section 312(c) of this title shall not apply in the case of the disability or death of a veteran as a result of non-Hodgkin's lymphoma if—

"(1) there is affirmative evidence that such disease was not incurred by the veteran during the performance of service in the Republic of Vietnam during the Vietnam era;

"(2) there is affirmative evidence to establish that an intercurrent injury or disease which is a recognized cause of the disease was suffered by the veteran between (A) the date of the veteran's latest departure from the Republic of Vietnam while in the active military, naval, or air service during the Vietnam era, and (B) the onset of the disease; or

"(3) the Administrator determines, based on evidence in the veteran's service records and other records of the Department of Defense, that the veteran was not exposed to herbicides while in the active military, naval, or air service in the Republic of Vietnam during the Vietnam era.".

SEC. 3. EFFECTIVE DATE.

The amendments made by section 2 shall take effect on October 1, 1987. No benefit may be paid for a period before that date by reason of the enactment of such amendments.

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II

100TH CONGRESS
1ST SESSION

S. 1787

To amend title 38, United States Code, to prescribe certain presumptions in the case of veterans who performed active service in Vietnam during the Vietnam era.

IN THE SENATE OF THE UNITED STATES

OCTOBER 14 (legislative day, OCTOBER 13), 1987

Mr. DASCHLE (for himself, Mr. KERRY, Mr. SIMON, Mr. WIRTH, Mr. HEINZ, Mr. SPECTER, and Mr. PRESSLER) introduced the following bill; which was read twice and referred to the Committee on Veterans' Affairs

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A BILL

To amend title 38, United States Code, to prescribe certain presumptions in the case of veterans who performed active service in Vietnam during the Vietnam era.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Veterans' Agent Orange Disabilities Act of 1987".

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) There is sufficient scientific evidence to warrant a presumption that dioxin or other toxic herbicides

used in support of United States and allied military operations in the Republic of Vietnam during the Vietnam era (A) causes non-Hodgkins lymphoma and lung cancer in humans who have been exposed to such herbicides, and (B) has disease-causing immunosuppressive effects on such humans.

(2) The Administrator of Veterans' Affairs has determined that it is reasonable to presume that any veteran who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era was exposed to dioxin or other toxic herbicides during such service.

SEC. 3. PRESUMPTION RELATING TO CERTAIN DISEASES.

(a) PRESUMPTION OF SERVICE CONNECTION.—Section 312 of title 38, United States Code, is amended by adding at the end the following new subsection:

"(c) For the purposes of section 310 of this title, in the case of any veteran who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era, the following diseases shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of such service:

"(1) Non-Hodgkin's lymphoma.

"(2) Lung cancer becoming manifest within 25 years after the last date on which the veteran performed such service in the Republic of Vietnam.

"(3) A disease that, in accordance with section 4 of the Veterans' Agent Orange Disabilities Act of 1987—

"(A) is determined to be reasonably associated with damage to or suppression of the human immune system resulting from exposure to dioxin or any other toxic herbicide used, during the Vietnam era, in support of United States and allied military operations in the Republic of Vietnam; and

"(B) is listed in regulations prescribed by the Administrator for the purpose of this subsection.".

(b) PRESUMPTION NOT REBUTTABLE.—Section 313 of title 38, United States Code, is amended by adding at the end the following new subsection:

"(c) Subsection (a) of this section shall not apply with respect to section 312(c) of this title.".

(c) APPLICABILITY OF PRESUMPTION.—If, in the case of any veteran, compensation under chapter 11 or disability and indemnity compensation under chapter 13 of title 38, United States Code, is awarded to any person on the basis of a presumption provided in section 312(c) of such title (as added by subsection (a)), such award shall take effect on the date (whether before, on, or after the date of the enactment of this Act) on which the Veterans' Administration first received an application in which such person claimed entitlement to such compensation on the basis of the disability or death of such veteran resulting from a disease referred to in such section 312(c).

SEC. 4. DISEASES ASSOCIATED WITH IMMUNOSUPPRESSIVE EFFECTS OF CERTAIN HERBICIDES.

(a) INITIAL DETERMINATIONS.—(1) Subject to paragraph (2), the Administrator shall enter into an agreement with an appropriate nonprofit private scientific organization that requires such organization—

(A) to conduct a survey of all completed and ongoing scientific studies of the effects that dioxin and other toxic herbicides used in support of United States and allied military operations in the Republic of Vietnam during the Vietnam era have on humans or other animals that have been exposed to such herbicides; and

(B) to determine in the case of each such herbicide, on the basis of such studies, what (if any) diseases are reasonably associated with damage to or suppression of the human immune system resulting from exposure to such herbicide.

(2) The nonprofit private scientific organization referred to in paragraph (1) shall be the National Academy of Sciences, except that the Administrator may enter into an agreement with any other appropriate nonprofit private scientific organization for purposes of such paragraph if—

(A) the National Academy of Sciences does not enter into an agreement with the Administrator under such paragraph;

(B) the Administrator has transmitted to the veterans' committees a notification, in writing, containing the name of the other organization; and

(C) ninety days have elapsed since the date on which the veterans' committees received the notification.

(3) Not later than one year after the date of the enactment of this Act, the scientific organization conducting the survey referred to in paragraph (1)(A) shall transmit to the Administrator and the veterans' committees a report, in writing, containing the name of each disease determined as provided in paragraph (1)(B) to be reasonably associated with damage to or suppression of the human immune system resulting from exposure to herbicides referred to in such subsection.

(4)(A) Not later than 90 days after the date on which the Administrator and the veterans' committees receive the report required by paragraph (3), the Administrator shall prescribe regulations for the purpose of section 312(c)(3) of title 38, United States Code (as added by section 3(a) of this Act), that lists each disease named in such report.

(B) Notwithstanding subparagraph (A), if, within 90 days after the date on which the Administrator and the veterans' committees receive the report required by paragraph (3), there is enacted a law that states that a specified disease shall not be included in regulations prescribed under that subparagraph, the Administrator may not include that disease in the regulations.

(b) ANNUAL REVISIONS.—(1) Subject to paragraph (2), the Administrator, in consultation with the head of an appropriate nonprofit private scientific organization, shall periodically (but not less often than annually)—

(A) survey any additional study described in subsection (a)(1)(A) that has been published or otherwise become available since the last survey under this section; and

(B) based on each such survey and previous surveys under this section, determine whether any diseases in addition to those previously determined under this section are reasonably associated with damage to or suppression of the human immune system resulting from exposure to a herbicide referred to in subsection (a)(1)(A).

(2) The nonprofit private scientific organization referred to in paragraph (1) shall be the National Academy of Sciences, except that the Administrator may consult with the head of any other appropriate nonprofit private scientific organization for purposes of such paragraph if—

(A) the President of the National Academy of Sciences declines to consult with the Administrator for such purposes;

(B) the Administrator has transmitted to the veterans' committees a notification, in writing, containing the name of the other organization; and

(C) ninety days have elapsed since the date on which the veterans' committees received the notification.

(3) After each survey under paragraph (1) (and not less often than annually), the Administrator shall transmit to the veterans' committees a report on such survey containing the name of any additional disease determined to be reasonably associated with damage to or suppression of the human immune system resulting from exposure to that herbicide.

(4) If a report under paragraph (3) contains the name of an additional disease, the Administrator, not later than 90 days after the date on which the veterans' committees re-

ceive that report, shall add that disease to the list of diseases contained in the regulations prescribed under subsection (a)(4).

(c) DEFINITION.—In this section, the term "veterans' committees" means the Committees on Veterans' Affairs of the Senate and the House of Representatives.

SEC. 5. RESULTS OF EXAMINATIONS AND TREATMENT OF VETERANS FOR DISABILITIES RELATED TO EXPOSURE TO CERTAIN HERBICIDES.

(a) IN GENERAL.—(1) Subchapter III of chapter 17 of title 38, United States Code, is amended by inserting after section 624 the following new section:

"§ 625. Reports on health care relating to exposure to certain toxic substances

"(a) The Administrator shall compile and analyze, on a continuing basis, all clinical data obtained by the Veterans' Administration in connection with physical examinations and treatment furnished by the Veterans' Administration after November 3, 1981, to veterans who are eligible to receive such examinations or treatment by reason of having been exposed to dioxin or any other toxic substance referred to in section 610(e)(1)(A) of this title.

"(b) The Administrator shall submit to the Committees on Veterans' Affairs of the Senate and the House of Representatives a semiannual report containing—

"(1) the information compiled in accordance with subsection (a) of this section;

"(2) the Administrator's analysis of such information;

"(3) a discussion of the disabilities identified or treated by the Veterans' Administration in the case of veterans referred to in subsection (a) of this section;

"(4) the Administrator's explanation for the incidence of such disabilities; and

"(5) other explanations for the incidence of such disabilities considered reasonable by the Administrator.".

(2) The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 624 the following new item:

"625. Reports on health care relating to exposure to certain toxic substances.".

(b) First Report.— The first report under section 625 of title 38, United States Code (as added by subsection (a)), shall be submitted one year after the date of the enactment of this Act.

SEC. 6. DEFINITIONS.

In this Act, the terms "Administrator", "veteran", and "Vietnam era" shall have the meanings given those terms in section 101 of title 38, United States Code.

Opening Statement
Senator Alan Cranston
Chairman
Committee on Veterans' Affairs

Hearing to Consider S. 1692, the proposed "Agent Orange Disability Benefits Act of 1987"; S. 1787, the proposed "Veterans' Agent Orange Disabilities Act of 1987"; and Agent Orange-Related Oversight Issues

May 12, 1988

Good morning. Welcome to today's hearing of the Committee on Veterans' Affairs on Agent Orange-related research, oversight issues, and legislation -- S. 1692, introduced by Senator Murkowski, and S. 1787, introduced by Senators Daschle and Kerry.

We have a great number of witnesses scheduled to testify this morning, including representatives from the Veterans' Administration (VA), scientific entities which have conducted or reviewed research related to the health effects of Agent Orange or other herbicides, representatives of veterans' service organizations and, I would particularly like to note, eight witnesses who either are Vietnam veterans or are representatives of Vietnam veteran or Agent Orange organizations.

Since Agent Orange first came to public attention in the late 1970s, I have been working to resolve the concerns raised about the possible adverse health effects arising from veterans' exposure to Agent Orange in Vietnam. These have been very emotional and controversial issues, and the inability to resolve them completely has undoubtedly contributed to a feeling on the part of some Vietnam veterans that they have not been treated fairly by the Nation for which they fought.

As either the Chairman or Ranking Democratic member of the Veterans' Affairs Committee, I have participated in numerous hearings and discussions on this issue, and I am proud to have authored in the Senate various measures which have sought to provide some solutions to the Agent Orange dilemma. These include measures enacted into law to accomplish the following: (1) provide veterans exposed to Agent Orange in Vietnam with eligibility for VA health care for the treatment of any condition that cannot be affirmatively related to some other cause (Public Laws 97-72, 99-166, and 99-72); (2) require the VA both to conduct an epidemiological study of Vietnam veterans to evaluate the health effects of their exposure to Agent Orange and to carry out a review of the literature on the health effects of such exposure (Public Law 96-151); and, later, authorize such study and literature reviews to cover the health effects of their overall experience in Vietnam (Public Law 97-72); and (3) require the VA through public rulemaking to develop policies and procedures for the adjudication of veterans' claims for compensation or other benefits based on their exposure to Agent Orange (Public Law 98-542; co-authored with then-Chairman Senator Simpson).

Our job is not complete, however. I feel that we must continue to work to ensure that all appropriate efforts are made to try to find answers to the questions that have been raised regarding the long-term effects of Agent Orange exposure, and to ensure that Vietnam veterans are treated fairly and compassionately. It is my hope that today's comprehensive hearing will help us towards those goals.

The questions which have been raised about the health effects of Agent Orange are scientific ones; they require scientific research and analysis. They are not susceptible to quick and easy answers. Rather, meaningful answers must be found, not just for purposes of providing compensation but so that we can know the full extent of any threat which may exist to the health of our Vietnam veterans. Accordingly, a major focus of my efforts and those of the Committees on Veterans' Affairs in both Houses has been on research which might eventually lead to a greater understanding of the health effects of Agent Orange exposure and how best to address the special needs of those veterans who may have been exposed to this herbicide.

A major focus of today's hearing therefore will be on the state of science relating to the human health effects of Agent Orange exposure in Vietnam. Numerous studies have been done regarding the effects of exposure to Agent Orange and its component parts and related phenoxy herbicides. The results from those studies have been conflicting and difficult to interpret. Although many of the studies reassuringly have found no adverse human health effects, others present more troubling suggestions that Agent Orange may be associated with an increased risk of certain diseases in humans. That many veterans believe that their or their children's health problems are related to Agent Orange exposure in Vietnam certainly is cause for great concern, and we owe it to them to continue to press for better answers than we now have.

We will hear testimony from the Centers for Disease Control (CDC), which has been responsible for conducting the epidemiological study mandated by Public Laws 96-151 and 97-72. The CDC will be describing the results of its Vietnam Experience Study, designed to demonstrate whether or not there is any difference in the health of veterans of the Vietnam era who served in Vietnam compared to the health of veterans who served elsewhere during the same period of time. VA scientists have completed a proportionate mortality of Vietnam veterans, and we will be hearing testimony about their findings as well.

In addition to studies of the effects of dioxin exposure on Vietnam veterans, other studies have examined the effects of herbicide exposure on agricultural, forestry, and industrial workers exposed occupationally. Some of these studies have found some excesses of certain diseases among exposed workers, while others have not. We will be hearing testimony on such research from the National Cancer Institute, the National Institute for Occupational Safety and Health (which is part of the CDC), the Environmental Protection Agency, and the Department of Agriculture.

In addition to hearing from those directly involved in conducting such research, we also will hear testimony from three entities -- the Office of Technology Assessment, the Agent Orange Working Group of the Domestic Policy Council, and the Veterans' Advisory Committee on Environmental Hazards -- with the scientific expertise to provide independent assessments of the significance of such research.

There is one aspect of this morning's testimony that requires special attention, I believe. In the Vietnam Experience Study, the CDC has found that 14.7 percent of the Vietnam veterans have experienced combat-related post-traumatic stress disorder at some time since their service and that 2.2 percent had this disorder during the month before their examination. These results are the latest -- and to this point, the most detailed -- findings that some Vietnam veterans have suffered and continue to suffer significant psychological problems related to their service in Vietnam. I intend to determine this morning whether these findings are borne out by the extensive PTSD study that Congress mandated the VA to carry out 4 years ago and which is being carried out by Research Triangle Institute.

From the very outset of my time in the Senate in 1969, I have been concerned about this issue. Although there were many delays before the VA got started, it has taken some appropriate steps to respond to the needs of these veterans, especially through the Vet Center program. However, more effort is still needed in terms of --

* increased efforts to provide a full range of care and treatment for veterans with PTSD, including specialized inpatient units;

* greater support for research into the disorder, a priority recognized by Congress just this month in sending H.R. 2616 to the President for signature;

* perfecting treatment methods; and

* ensuring better coordination and cooperation between those in the VA responsible for providing treatment and those responsible for adjudicating claims for benefits.

Our Committee had already scheduled an oversight hearing for July 7 to consider these and other PTSD issues. That hearing takes on a new urgency in light of the CDC findings.

I urge the VA to evaluate carefully these CDC findings as well as the soon-to-be released results from the VA's PTSD study, both in the context of submitting any proposals relating to the future of the Vet Center program, such as are called for in H.R. 2616, and generally as the agency seeks to meet the needs of Vietnam veterans. I further urge the VA to be prepared, as soon as possible and certainly by the July 7 hearing, to respond in detail to the many findings and recommendations that the Chief Medical Director's Special Committee on PTSD has made in its four reports.

Healing the wounds of war must be the VA's primary responsibility, and the findings on PTSD again highlight one area that demands special attention in this regard.

I recognize that the issue of veterans' exposure to Agent Orange through their service in Vietnam is an emotional and divisive one for many Vietnam veterans, as well as for their families and others. I believe this hearing would not be complete -- or fair -- without providing them the opportunity to present first-hand their concerns about these issues.

I am sure that the result which we all hope for from the scientific studies is a finding that exposure to Agent Orange or service generally in Vietnam does not portend an increased risk of various diseases. However, if such risk does exist, we must see to it that our veterans are treated appropriately and fairly. I hope that this hearing will provide a clearer picture of the overall state of science on this issue and will aid us in our efforts to grapple with this very complicated, divisive, intensely felt, vitally important issue.

AGENT ORANGE HEARING INTRODUCTORY STATEMENT
BY SENATOR SPARK MATSUNAGA
SENATE VETERANS' AFFAIRS COMMITTEE
MAY 12, 1988
SD-430

THANK YOU, MR. CHAIRMAN.

I'D LIKE TO EXTEND MY WELCOME AND THANKS TO THE MANY WITNESSES WHO HAVE AGREED TO TESTIFY BEFORE THE COMMITTEE ON THIS DIFFICULT MATTER. IN PARTICULAR, I WISH TO EXTEND MY THANKS TO ADMIRAL ELMO ZUMWALT, WHOSE RECORD OF OUTSTANDING SERVICE TO THE NATION ONLY HIGHLIGHTS THE SPECIAL CIRCUMSTANCES THAT BRING HIM BEFORE US TODAY. HE AND HIS SON, MORE THAN ANY OTHER, HAVE DRAWN THE ATTENTION OF THE AMERICAN PEOPLE TO THE ISSUE BEFORE US. THEY BOTH DESERVE OUR DEEPEST SYMPATHY AND GRATITUDE.

MR. CHAIRMAN, I WILL BE BRIEF. FOR MANY YEARS NOW THE CAUSAL RELATIONSHIP BETWEEN AGENT ORANGE EXPOSURE AND DISEASE HAS BEEN AN ISSUE OF GREAT CONTROVERSY. MANY STUDIES AND TENS OF MILLIONS OF DOLLARS LATER, WE ARE STILL FAR FROM CONCLUSIVELY PROVING OR DISPROVING THAT CONNECTION. AFTER ALL THIS TIME, RESEARCH HAS BEEN HAMPERED BY SUCH FUNDAMENTAL PROBLEMS AS DETERMINING WHO MAY HAVE BEEN EXPOSED TO AGENT ORANGE, OR WHAT AMOUNT OF THE HERBICIDE OR ITS POTENTIALLY TOXIC COMPONENTS, INCLUDING DIOXIN, MAY HAVE BEEN RETAINED IN THEIR BODIES, OR HOW DIOXIN IS RELATED TO PARTICULAR DISEASES.

THE STATE OF OUR KNOWLEDGE ON THIS SUBJECT IS SO LACKING IN CERTAINTY, SO AMBIGUOUS, THAT I AM BEGINNING TO WONDER IF WE SHOULD NOT AGREE WITH THOSE WHO SAY THAT CAUSAL RELATIONSHIP BETWEEN AGENT ORANGE AND SPECIFIC DISABILITIES MAY NEVER BE PROVED AND THEREFORE MUST BE PRESUMED. THIS ARGUMENT IS ESPECIALLY PERSUASIVE WHEN ONE CONSIDERS THAT THE ALLEGED VICTIMS OF THE HERBICIDE ARE NOT GETTING ANY YOUNGER. ARE WE GOING TO WAIT DECADES FOR ABSOLUTE EVIDENCE THAT MIGHT NEVER APPEAR? AND WHAT IF THAT EVIDENCE DOES SHOW UP? WHAT IF WE DISCOVER ABSOLUTE PROOF IN 2010 THAT VETERANS WHO DIED IN 1989 WERE VICTIMS OF DIOXIN-GENERATED CANCERS? HOW DO WE COMPENSATE THEM?

MR. CHAIRMAN, IN THIS SENSE THE SITUATION OF THE AGENT ORANGE VETERANS HAS SOME RESONANCE WITH THE SITUATION OF ATOMIC VETERANS. LARGELY DUE TO YOUR EFFORTS, BOTH HOUSES OF CONGRESS RECENTLY APPROVED LANDMARK RADIATION COMPENSATION LEGISLATION. I WONDER IF THE TIME HAS NOT COME FOR ACTIVE CONSIDERATION OF A SIMILAR AGENT ORANGE COMPENSATION MEASURE. THIS THOUGHT WAS BEHIND MY COSPONSORSHIP OF S.1787, THE DASCHLE-KERRY COMPENSATION BILL.

THANK YOU, MR. CHAIRMAN. I LOOK FORWARD TO THE CONSTRUCTIVE DIALOGUE THAT THIS HEARING WILL NO DOUBT GENERATE.

# # #

Statement
Senator George J. Mitchell
Committee on Veterans' Affairs
May 12, 1988

Mr. Chairman, I commend you for scheduling this morning's hearing. It's a full agenda facing the committee so I will make only brief remarks.

Over the next several hours we will:

1) examine the status of the various Federal Government-sponsored research efforts on Agent Orange and

2) review the various bills, S 1692, introduced by our distinguished ranking member, Frank Murkowski, and S 1787, introduced by Tom Daschle and John Kerry, that would provide service-connected compensation to veterans who suffer from certain listed diseases or illnesses presumed to be associated with exposure to Agent Orange.

Mr. Chairman, as you know all too well, the search to identify the adverse health effects which may now afflict veterans based on their exposure to Agent Orange as far back as 1962 has been long, difficult, and exceptionally painful.

Unfortunately, it's also far from concluded.

Congress last grappled with the issue of Agent Orange service-connection, in Public Law 98-542, when it provided temporary compensation benefits for veterans suffering from chloracne or porphyria cutanea tarda if either disease became manifest within one year after departure from Vietnam.

It also told the VA to undertake public rulemaking to develop regulations for resolving Agent Orange claims and in that process to specifically address whether chloracne, porphyria cutanea tarda and soft-tissue sarcoma which were then thought to be "highly-associated" with exposure to Agent Orange should be presumed to be service-connected.

It's my understanding that no compensation payments were made under this authority. But, as indicated by this morning's testimony by Tom Harvey, the agency's Deputy Administrator, the VA feels it is fully meeting its obligations to provide service-connected compensation when merited by the circumstances.

The VA says the low success rate of Agent Orange-related claims can be explained because

1) the evidence says veterans did not have a substantial opportunity for significant exposure to Agent Orange, and

2) there is no conclusive evidence establishing a relationship between Agent Orange and various health problems, with the exception of chloracne, if manifested within three months from service in Vietnam.

But every member of this committee has heard from veterans who believe that their exposure to Agent Orange in Vietnam has resulted in serious adverse health effects for them and, in some cases, their children.

The diseases or disabilities that have been attributed to Agent Orange include skin conditions, cancers, fatigue, nervousness, numbness in the extremities, vision and/or hearing impairments and birth defects.

While these veterans are eligible for VA medical care on the basis of their exposure to Agent Orange, they have been spectacularly unsuccessful in their efforts to have the VA provide service-connection compensation for their health problems. And they are angry at the system which they believe denies them benefits but doesn't resolve the many questions surrounding the possible relationship between Agent Orange and a number of diseases or adverse health affects.

That is the situation facing us this morning as we begin these hearings. And I'm frank to say, Mr. Chairman, it's highly uncertain where we will go from here.

I do know that we all hope that the testimony of the numerous witnesses this morning can provide the committee sufficient information on the relationship between exposure to Agent Orange and one's health and the manner in which the ongoing research efforts have been conducted for us to make well-reasoned judgements on how to proceed on this issue.

And after evaluating the information and making our individual judgements, I have little doubt, Mr. Chairman, that this committee will join together in an effort to plot a course of action that will provide peace of mind to all veterans touched by this controversy and will allow the controversy to be resolved in a manner that reflects the basic sense of justice on which this nation prides itself.

REMARKS: HEARING ON AGENT ORANGE
SENATOR JOHN D. ROCKEFELLER IV
May 12, 1988

Thank you, Mr. Chairman.

This hearing is on a subject that everyone in this room takes very seriously. There may be disagreement or differing views on what actions should be taken at this particular time by Congress affecting veterans exposed to Agent Orange. But the history of the past nine years shows that Congress, veterans groups, and the research community have devoted an enormous amount of effort and time to address the issues involved with Agent Orange.

Personally, I have some history as well in this issue. I remember vividly when our Vietnam veterans returned. After a painful period when these honorable men and women felt neglected and even stigmatized, eventually the American people began to pay attention and finally pay tribute to our veterans of the Vietnam era.

I was Governor of West Virginia when both the honor owed to, and the needs of, Vietnam veterans aroused people's consciousness. West Virginia suffered painfully during the Vietnam war. Our state had the highest rate of combat casualties in Vietnam. Over 40,000 of our citizens living today served in that war.

With veterans groups in our state, I worked on a number of efforts to both recognize our Vietnam veterans and provide the medical, job training, and other services they so obviously deserved.

Related to this morning, in 1982, I started a special Agent Orange Assistance program, as part of our Health Department. That program exists still today, and is in fact recognized as one of the leading and most active efforts in any state in the country to work with Vietnam veterans who believe they were exposed to Agent Orange. Its director, Chuck Conroy, is a nationally recognized expert in Agent Orange issues and sits on advisory committees to several of the major research efforts looking at these issues. West Virginia's Agent Orange program places special emphasis on outreach to Vietnam veterans, to match them up with VA hospitals and other medical services for checkups and intensive monitoring of their health. They have done this not only to help the veteran but also to contribute to research by gathering clues on what impact Agent Orange has had on the health of Vietnam veterans and their offspring.

I am really puzzled about this debate –– the debate about what we know and whether we know about the linkages between Agent Orange exposure and illnesses or diseases that emerge among Vietnam veterans. It's a question that we have to try to answer. I know some believe we have the information and evidence to justify legislation to grant presumptions of service–connected disability to

Vietnam veterans. It is time to take a serious look at the arguments supporting this kind of legislation, and sort out why there is so much disagreement about what all the studies and research have to tell us.

I sincerely wish the answers were obvious. I do know that we have a responsibility to do everything in our power to extend both assistance and justice to veterans who served in Vietnam. Much has been put in place through legislation over the past decade and more. Today, we must consider whether other steps are in order.

United States Senate
WASHINGTON, D.C. 20510

STATEMENT OF SENATOR TOM DASCHLE

BEFORE THE COMMITTEE ON VETERANS' AFFAIRS

MAY 12, 1988

Mr. Chairman, thank you for the opportunity to appear today to discuss the continuing problem of Agent Orange and its effects on Vietnam veterans. I would like to focus attention on S. 1787, the bill Senator Kerry and I have introduced to establish, for disability compensation purposes, a presumption in favor of Vietnam veterans suffering from diseases associated with exposure to Agent Orange. I am confident that my colleagues will find the case for compensation compelling once the full truth is known about current dioxin research and the government's treatment of this issue, which has been, at best, woefully inadequate.

The Vietnam War ended long ago, but many Vietnam veterans continue to fight a seemingly endless battle against bureaucratic intransigence -- a battle for government recognition of what they firmly believe are service-connected disabilities due to exposure to Agent Orange. It is a battle in which the veterans can hope to win only a partial victory, for even compensation will not erase the hurt caused by a combination of disease and government insensitivity.

There are encouraging signs, however, that some in the government are finally responding more effectively to this problem. Until recently, the government has consistently argued that few veterans were exposed to substantial levels of Agent Orange, that those most heavily exposed were the "Ranch Handers," who executed the Air Force defoliation and crop destruction missions, and that studies show the Ranch Handers are not suffering from any significant increase in major illnesses. Those making this argument have relied heavily on reports that the Air Force's 1984 "Ranch Hand" Report was "negative" and "should be viewed as reassuring to the Ranch Handers and to their families."

In February 1988 the Air Force issued an interim report on the Air Force Health Study (Ranch Hand Report) entitled "United States Air Force Personnel and Exposure to Herbicide Orange." This report offers a reassessment of the original "negative" study, pointing out important new evidence and drawing a very different conclusion. While the 1984 report found a statistically significant increase among the Ranch Hand population in birth defects and cancers, the report downplayed the significance of those findings, suggesting that might be explained away in further review. The report noted that birth defects were self-reported and, thus, needed to be verified by record review, and that they appeared to be limited to minor skin defects. The report also noted that cancers were also limited to the skin and that they were probably due to overexposure to the sun.

The February 1988 report provides a long-overdue update. According to this report and information I have received from the Air Force, positive reports of birth defects have been verified, and the defects are not limited to the skin. There are major birth defects in the Ranch Hand children, and it appears that the overall birth defect rate is approximately twice the rate of birth defects in the control group. The skin cancers cannot be explained by overexposure to the sun, and an increase in systemic cancers cannot be ruled out.

The 1988 report also explains the inherent problems in the study's current method for identifying exposure (the Air Force is developing a new exposure index based on dioxin levels in the blood), and takes a special look at health effects generally associated with dioxin exposure. Finally, the report's abstract concludes that "dioxin is not exonerated as a causative agent."

It is also important to note that the 1987 VA Mortality Study released reluctantly by the VA last fall found that Marine troops serving in an area of I Corps sprayed heavily with Agent Orange had a 110% higher rate of death from non-Hodgkin's lymphoma than their Army counterparts who served in less heavily sprayed areas. The Marines also suffered from a 58% higher death rate from lung cancer than the Army veterans.

Agent Orange victims ask only to be given accurate, timely information about their health and to be treated fairly within the Veterans Administration (VA) disability compensation system. Because many of their disabilities manifest themselves years after their military service, they have been asked to "prove" that their illnesses are service-connected. That is a standard to which other veterans are not held.

In the cases of veterans whose disabilities are caused by enemy fire, there is little question of their relationship to military service. For the sake of argument, I will not compare Agent Orange victims to those veterans, though their pain and injuries are no less real. I will, instead, compare Agent Orange victims to veterans with multiple sclerosis, or those with diabetes contracted within seven years of service, or POWs with spastic colon. All these veterans have been granted a presumption of service-connected disability, though many might find the scientific evidence linking their disabilities to service weaker than the evidence suggesting a relationship between certain disabilities and exposure to Agent Orange.

S. 1787 is a reasonable approach to a very difficult problem. It is not rigid and uncompromising in its identification of diseases to be considered for compensation. It does not close its eyes to the need for continued scientific inquiry into the effects of dioxin. Moreover, it is not a bill which takes lightly our obligation to exercise restraint in spending federal funds.

S. 1787 would presume that non-Hodgkin's lymphoma and lung cancer manifested within 25 years of service, both clearly linked in the scientific literature to dioxin exposure, are service-connected disabilities to be compensable under the VA disability compensation system for those veterans who, based on current VA regulations, were exposed to Agent Orange. The bill would also establish a procedure for identifying immune system disorders which might, in the future, be compensable. Finally, the bill would require that the VA make a careful and concerted effort to gather and analyze information about the medical treatment of veterans' disabilities which may have been caused by exposure to Agent Orange and other toxic herbicides.

Does the scientific evidence of Agent Orange toxicity support the presumption provided in S. 1787? Numerous studies on animals make it abundantly clear that dioxin -- the contaminant of Agent Orange most often alleged to have harmful effects -- is an extremely toxic substance. The precise level of toxicity varies from species to species, but the evidence of harm is incontrovertible. For some species of guinea pigs, minute quantities of dioxin are sufficient to cause immediate death.

Are humans at risk from dioxin exposure? Some studies have been inconclusive, but many others have provided strongly suggestive -- and frightening -- evidence of the tragic effects of dioxin exposure. Various studies of men and women exposed to dioxin, including those of American soldiers in Vietnam, have linked the chemical to health problems ranging from skin disorders to liver damage to cancer to birth defects. The Environmental Protection Agency puts dioxin at the very top of its list of carcinogens and requires its dioxin researchers to wear "moon suits" to prevent contact of any kind while handling the substance.

No one should miscontrue S. 1787 as a statement that dioxin research should stop. I will continue to support an aggressive research effort, and I greatly appreciate the work of those scientists, in the Air Force and in the scientific community at large, who are working to uncover the full extent of dioxin's effects. Indeed, I am gratified to see that the scientists who have worked on the Agent Orange problem appear to be coming together to help us answer these difficult questions. Our job is to 1) oversee these studies, ensuring that valid scientific efforts will be freed from the interference of those who feel threatened by the results of objective scientific inquiry; and 2) promote a sound, cautious policy to meet the public health and environmental concerns related to dioxin.

Will the scientists here today claim that the link between dioxin and disease is definitive, that a simple cause and effect relationship has been irrefutably established? No. It is far too easy, in fact, to argue that more time is needed to study the problem, that more time is needed to ensure that money is not paid to veterans who don't deserve compensation. Indeed, there are those who would wait for science to "prove" beyond a shadow of doubt that dioxin is a killer.

I submit that we will be waiting for a very long time, and at an unacceptable human cost.

There is a time for study and more study, and there is a time for leadership. We cannot wait for science to dictate this policy. As United States Senators, we must be willing to act on behalf of our nation's veterans while that action can still be meaningful.

Are we so afraid of being wrong that we are unwilling to risk being right?

Public Law 98-542 specifies that in compensation cases where there is reasonable doubt, the benefit of the doubt shall be awarded to the veteran. Mr. Chairman, the evidence supporting the claims of Agent Orange victims far exceeds this "reasonable doubt" standard. Our policy choice is clear: Do we give the benefit of the doubt to the veterans or the VA? As a member of Congress, I have faced this choice for almost ten years. Based on the preponderence of evidence I have seen, the choice has not been difficult for me. I decided some time ago that if I am going to err in this case, I will err on the side of caution and compassion. It is time to grant meaningful compensation to Agent Orange victims.

In conclusion, Mr. Chairman, I want to thank you for conducting this hearing. S. 1787 represents an attempt to address the Agent Orange problem in a comprehensive fashion. I welcome suggestions as to how the bill could be improved. If there are legitimate concerns about specific language in the bill, I am hopeful this hearing will provide an opportunity to consider them. In the process, however, we should not forget that many Vietnam veterans are suffering -- some dying -- as we debate the most effective, compassionate way to deal with this problem.

THOMAS DASCHLE
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ADDITIONAL STATEMENT OF SENATOR TOM DASCHLE
BEFORE THE SENATE VETERANS' AFFAIRS COMMITTEE
FOR THE MAY 12, 1988 AGENT ORANGE HEARING RECORD

Mr. Chairman, let me thank you and the ranking minority member, Senator Murkowski, for allowing me to testify and sit as a guest of your committee during the May 12, 1988, Agent Orange hearing. As you know, this issue is very important to me, and I deeply appreciate the opportunity to participate actively with you and other committee members.

The hearing was an important step toward updating members of Congress, veterans, and the general public on the status of Agent Orange-related studies and legislation to address the issue of compensation for veterans' disabilities that may be attributable to exposure to Agent Orange. Nevertheless, I remain concerned about some of the testimony that was inconsistent with reports I have been given on the status and details of several of the studies covered in the hearing. For the hearing record, I am submitting my review of those discrepancies and a few additional comments on the Agent Orange issue. I am also submitting the enclosed written followup questions for several of the witnesses.

First, as I mentioned in the hearing, I am disturbed by the comment by the Deputy Administrator of the VA, Thomas E. Harvey, that there is not a "shred of evidence" linking dioxin with supression of the immune system. I am enclosing a partial bibliography of studies relating dioxin with suppression of the immune system.

I would also refer the Committee and Mr. Harvey to the testimony of Dr. Tom Gasiewicz, Associate Professor of Toxicology at the University of Rochester, and the "Immunotoxicity" section of the VA's "Review of Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins (Volume IX: Analysis of Literature on Health Effects Published in 1986)," dated May 26, 1987. In its conclusions, the VA's own literature review states, "Although no study has provided direct evidence of immune suppression in humans exposed to chlorinated dibenzo-p-dioxins and/or phenoxy herbicides, the indirect evidence that human immune suppression might result from exposure to these compounds is increasing." I stand by my claim that there is more than a "shred of evidence" linking dioxin with suppression of the immune system.

The comments by the Chairman of the White House Agent Orange Working Group, Don M. Newman, that "service in Vietnam and possible exposure to Agent Orange are not resulting in adverse health effects," and "in the studies which have come to conclusion, we are seeing no cause-effect relationship between service in Vietnam and possible exposure to Agent Orange and adverse health," epitomize this Administration's tendency to oversimplify, downplay, or blatantly misrepresent scientific evidence suggestive of a link between negative health effects and exposure to dioxin. This is certainly not a minor concern, given the important implications this issue has for veterans, their families, the environment, and public health. While I am pleased that Mr. Newman retreated somewhat from his "no causal link" position under questioning, his prepared statements appear to represent a deliberate attempt to, at the very least, soften the public view of dioxin studies.

While I am not a scientist, one thing I have clearly learned from my work on this issue is epidemiology is both extremely complex and severely limited in its ability to either prove or disprove a causal link between exposure to a substance and health effects. Science may never give us a definitive answer. Furthermore, an understanding of the importance of an accurate exposure index is vital to an understanding of the issue. I think it is important to point out, therefore, that none of the federal studies to date have provided accurate exposure indices. The absence of such indices tends to allow for misclassification in "exposed" and "control" groups, and that misclassification tends to hide any potential dioxin effects or dose-response relationships.

Perhaps one of the most disturbing statements at the hearing was made by General Alexander M. Sloan, who testified on behalf of the Air Force. General Sloan stated that self-reported birth defects in the 1984 "Baseline Morbidity Study Results" of the Air Force Ranch Hand Study have not yet been verified. I submit for the record a joint letter to me, dated August 25, 1987, from Dr. Joel Michalek, Dr. Richard Albanese, and Col. William Wolfe, signed by Col. Wolfe, stating quite clearly that "Verification of all reported birth defects in the children fathered by participants in our study was conducted using medical records and birth certificates in 1984....A report of the analyses of these data was submitted to the Advisory Committee in 1984 but they recommended that it not be published."

General Sloan's statement, in conjunction with his testimony that the information and conclusions in the Air Force's 1988 interim report on the Ranch Hand Study "were essentially the same as in previous reports" causes me great concern about apparent Air Force management attempts to misrepresent, delay, or cloud reports concerning the Ranch Hand Study. The Air Force statements are especially perplexing in light of the fact that the Air Force attended a meeting in my office in January of this year to explain to me the Air Force's refusal to release the four-year-old report on birth defects. In fact, the 1988 interim report was released, in part, due to my request for a public update on this as yet unreported information.

It is important to note that while I was disappointed in some of the Air Force testimony, I was pleased that the Air Force scientists confirmed several important points: 1) that the excess in birth defects -- an approximate doubling -- in the Ranch Hand population is an important finding of which veterans should be aware; 2) that the exposure index currently used in the Ranch Hand Study has serious deficiencies that limit the study's ability to detect potential group differences and dioxin effects; 3) that some, but certainly not all, of the Ranch Handers were heavily exposed to Agent Orange; and 4) that Dr. Wolfe, Dr. Michalek, and Dr. Albanese collaborated on the 1988 interim report and agree on the technical merit and substance of this official Air Force report.

Although I continue to be concerned about Air Force management and Peer Review Group bias in the Ranch Hand Study, I have been very favorably impressed with the work of the Air Force scientists themselves. Their commitment to an improved exposure index based, at least in part, on actual body burdens of dioxin is encouraging and will take some of the guesswork out of exposure estimates, which, according to virtually every scientist I have talked to, have been notoriously poor. In fact, in spite of the deficiencies in the current Ranch Hand exposure index, there are indications that it is better than other exposure indices, such as the one attempted by the Centers for Disease Control in its aborted Agent Orange Exposure Study. As you know, I strongly support the Air Force project to determine actual dioxin levels of participants in the Ranch Hand Study and have pledged to support full funding for this effort.

The Air Force's blood studies should allow the Ranch Hand scientists to establish an exposure index based on actual dioxin levels. It will be interesting to see whether or not patterns of exposure emerge from these data. Since not all of the Ranch Handers were heavily exposed, it is possible that dioxin levels will correspond with certain occupations. We know from initial Air Force tests that several of the Ranch Hand enlisted ground crew had high exposures, and it will be important to see how the exposures of the pilots and the enlisted flyers compare with those of the ground crew.

Discussion of the National Cancer Institute's study of the effects of dioxin-laced 2,4-D on the health of Kansas farmers was also provocative. While a representative of the VA's Advisory Committee on Environmental Hazards suggested that there is conclusive evidence that "Vietnam veterans have not suffered adverse health effects as a result of their exposure to Agent Orange," he also conceded the strength of the Kansas farmer study, which detected a twofold increase in non-Hodgkin's lymphoma in the exposed farmers. In addition, he and the representative from the Office of Technology Assessment, Hellen Gelband, stated that it may be relevant to extrapolate from the Kansas study an increased risk of non-Hodgkin's lymphoma in certain portions of the Ranch Hand population or other veterans with high exposures to Agent Orange. This appears to me a tacit admission of the potential adverse effects of at least high exposures to Agent Orange.

It was also interesting to note the conflicting reports on whether or not the 2,4-D mixture in the Kansas study had dioxin in it. It would seem that the answer would be unequivocal on that point. Nevertheless, we witnessed attempts to characterize the study as somehow unrelated because "there was no dioxin in the mixture." We discovered, in fact, that dioxin, though not the 2,3,7,8 TCDD compound considered most dangerous, was in the mixture. There seem to be four possible conclusions to be drawn from the Kansas results: 1) the increase in non-Hodgkin's lymphoma is unrelated to the 2,4-D/dioxin mixture; 2) 2,4-D is the cause of the increase; 3) 2,4-D and dioxin worked together to cause the increase; or 4) dioxin is the cause, indicating negative health effects could result from dioxin doses even smaller and weaker than those in the Agent Orange mixture.

As for the assessments of the VA's Proportionate Mortality Study, it was encouraging to hear government witnesses acknowledge that there is "something special" about the Marines in the study. The "special" findings were cited as possibly attributable to Agent Orange, even by a representative of the VA's Advisory Committee on Environmental Hazards. It seems clear from the testimony that this study should not be ignored.

The lung cancer finding from the VA study was questioned by many who expressed concern that the data were not adjusted for smoking histories. I understand this concern and believe that adjusted analyses should be used whenever possible. It is difficult to adjust for smoking histories in a deceased population, however, and I am informed that the VA scientists did attempt to address this issue in other ways. First, they observed the death records of Army veterans in areas less heavily sprayed with Agent Orange and found no corresponding increase in lung cancers. The scientists said they had no reason to assume that Marine veterans smoked more than Army veterans. In addition, the VA scientists studied the data on other diseases reasonably associated with smoking, such as emphysema, and observed no corresponding increases in those diseases among the Marine veterans.

The discussion of the importance of adjusting the VA lung cancer data for smoking histories brings up a related issue: statistically significant findings in the Ranch Hand Study suggesting adverse health effects in the Ranch Hand population. Although several witnesses suggested that there are no statistically significant group differences adversely affecting the Ranch Hand group, this is not the case.

The 1988 Air Force interim report and the 1987 Morbidity Followup results show group differences in several important areas reasonably associated with dioxin exposure in the literature, including cancers and birth defects. While the Air Force has made a point to claim that group differences are "going away," a look at the adjusted analysis in the Ranch Hand Study would suggest that there are important group differences, such as a statistically significant increase in systemic cancers in the Ranch Hand enlisted flyers, the men who served in the back of the planes and controlled the release of Agent Orange. The importance of adjusted analyses, therefore, is important for all studies, not just the VA Mortality Study.

The fact that one of the witnesses claiming there are no significant health problems in the Ranch Hand population is the President of the Ranch Hand Vietnam Association, Major Jack Spey, is especially disconcerting. Major Spey authors newsletters to the members of the Ranch Hand Association and provides a major source of their information on this issue. It appears that Major Spey has been misinformed about the potential health risks facing the Ranch Hand population and has passed that "good news" along to the Ranch Handers.

It seems to me the only way to avoid this kind of situation is to ensure accurate, timely information -- the good and bad news -- to the Ranch Handers and any other population at a potential health risk.

While I have not yet had a chance to review the entire Vietnam Experience Study conducted by the Centers for Disease Control (CDC), I am troubled by the way in which the study has been reported. First, it is important to emphasize that the study is not an Agent Orange study and lacks the statistical power to detect many of the potential health effects associated with Agent Orange exposure. Furthermore, statistically significant findings seem to have been treated in a less than even-handed way, and there is an apparent desire to scrutinize the positive findings until they can be explained away. One example is the group difference (six cases to one) in non-Hodgkin's lymphoma reflecting a substantial increase in the Vietnam veterans. The CDC witnesses did not give much weight to these findings, claiming three of the cases have not yet been confirmed.

The birth defects data is another example of particular concern to me. While the Vietnam veterans reported a statistically significant increase in birth defects in their children as compared to the non-Vietnam veterans, the Centers for Disease Control (CDC) explains that the non-Vietnam veterans apparently underreported birth defects in their children and that hospital birth records do not verify the reported increase. What is not explained is that only a small, non-random sub-sample of the birth records were checked. As I understand it, there are two problems with this approach: 1) it would be preferable to verify all birth defects, or at least a larger, random sub-sample; and 2) it would be preferable to verify the birth defects through the use of current medical records or examinations instead of hospital birth records, which would not reflect learning disabilities or other birth defects not readily apparent at birth.

Another CDC study mentioned at the hearing was the aborted Agent Orange Exposure Study. As a prime sponsor of legislation mandating that study, I continue to be amazed at the way it has been handled. While it is difficult for me and many others to understand how CDC could spend years and millions of dollars only to fail to find enough exposed veterans to conduct a valid study, my strongest frustration regarding this study is that CDC and others have insisted on drawing conclusions about Agent Orange exposure from a study that was never actually conducted. The CDC "hit model" used to identify exposure was recognized by CDC as flawed. To "correct" the flaws, CDC took 665 of the veterans identified by the flawed hit model and tested the dioxin levels in their blood. When they found "normal" dioxin levels in these veterans, they concluded that a valid ground troop study could not be conducted and that the blood tests proved that ground troops weren't exposed to Agent Orange to any substantial degree.

Since the 665 veterans were identified by the flawed hit model, the only thing that could be "proved" by the blood tests was that the original method for identifying exposure was faulty -- far more faulty than the Air Force's current, limited exposure index. It is amazing to me that CDC, OTA, and the AOWG are willing to accept this failed study as "proof" of a lack of veterans' exposure to dioxin. I would refer the Committee to the March 18, 1988, issue of the Journal of the American Medical Association for a more complete explanation by Dr. Peter Kahn and his associates of the pitfalls of the CDC study.

Finally, I want to call to the Committee's attention my strong belief that peer review and monitoring standards in government Agent Orange and dioxin studies need to be reassessed. Obviously, high peer review standards need to be maintained in order to ensure that the public has the benefit of good science. I am deeply concerned about government interference in dioxin studies -- from the Office of Management and Budget, which has blocked funding for certain studies and suggested that there has been "enough" dioxin research, to the White House Agent Orange Working Group. I think Congress should pay particular attention to the VA's Advisory Committee on Environmental Hazards and the Ranch Hand Advisory Committee, both of which are involved in peer review of numerous government studies. If we want government science to be taken seriously, we need to ensure that these studies are conducted as freely and independently as possible.

In the specific case of the Air Force Ranch Hand Study, I am aware of a clear protocol violation with respect to the peer review group, which is chaired by a White House appointee. Page 89 of the protocol describes the "monitoring group": "Approximately equal representation will be maintained between government scientists, academic scientists, and scientific personnel nominated by veterans advocacy groups." The Air Force scientists have confirmed that there are no scientists on the peer review group who have been nominated by veterans' advocacy groups. This seems to me something that should have been corrected years ago and should certainly be corrected now.

Other peer review group behavior of concern is the Ranch Hand Advisory Committee's direction to the Air Force scientists in 1984 that the Baseline Morbidity Report's final conclusion that "It is incorrect to interpret this baseline study as 'negative,'" should be deleted. As you know, the study was later called "negative" by the Administration, and it has taken the Air Force four years to state in its 1988 interim report what the Air Force scientists tried to state in its original 1984 report -- that dioxin cannot be exonerated as a causative agent in negative health effects. The peer review group at one point tried to discontinue verification of the reported birth defects and recommended that the 1984 report of birth defects and the 1988 interim report not be published.

These are some of my concerns about the Agent Orange issue. As you can see, it is far from resolved, as the Senator from Wyoming suggested. I hope to work with you and the other Committee members in the coming months to address these very important matters.

Once again, thank you for your consideration and your work on behalf of America's veterans.

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* This article utilizes data from an unpublished Air Force Report dated December 17, 1984, and titled, "Reproductive Outcome Update." The report was prepared at the USAF School of Aerospace Medicine. According to the Air Force, the unpublished report is a working draft that includes data on the verification of the positive parental reports of birth defects in children of the Ranch Hand veteran and comparison veteran populations. A final report to include the verification of negative parental reports on birth defects has not been issued. Air Force scientists have confirmed that the unpublished report documents an approximate doubling of birth defects in the Ranch Hand Children.

NOTE: Attached is an Army Times article dated November 16, 1987, which describes Vietnamese studies relating dioxin exposure to increases in birth defects, stillbirths, and spontaneous abortions.

Army Times, 11/16/87

Studies of Vietnamese Show Agent Orange Link

By VESTA KIMBLE
Times Staff Writer

NEW ORLEANS — Studies on civilians who live in areas sprayed with Agent Orange during the Vietnam War could help determine whether American soldiers who occupied sprayed areas or handled the herbicide are at increased health risk, according to recent reports from Vietnamese physicians and scientists.

The reports, presented to a meeting here of the American Public Health Association, suggest there is a link between high levels of dioxin measured in the fat tissues of Vietnamese civilians and high rates of reproductive disorders, including stillbirths, birth defects and spontaneous abortions.

The scientists told the meeting of health professionals that Vietnamese civilians living in areas that were sprayed show high rates of liver cancer and reproductive abnormalities. Separate studies of fat tissue samples, conducted by an American scientist, show a higher concentration of dioxin among residents in south Vietnam, where the herbicide was sprayed, than in residents in north Vietnam, where Agent Orange was not sprayed.

Dr. Arnold J. Schecter, an American scientist who conducted the tissue studies in Vietnam during the last three years, told the meeting of health professionals that 100 Vietnamese civilians, who reported they were sprayed with the herbicide during the war, were found to contain an average of 22 parts per trillion of the dioxin found in Agent Orange in their fat tissues. The levels were as high as 103 parts per trillion for some civilians who were tested.

Those levels compared to 2-3 parts per trillion among residents in the northern city of Hanoi, which was not sprayed. Residents in industrial nations, such as the United States, are known to have levels of dioxin ranging from 4-7 parts per trillion, Schecter said.

In research studies on civilians living in sprayed and unsprayed areas in southern regions of Vietnam, physicians in Vietnam found there was a higher rate of abnormal births among residents in a sprayed village than among residents in Ho Chi Minh City (formerly Saigon), which was not sprayed.

Dr. Nguyen Thi Ngoc Phuong, a pediatrician and obstetrician in Ho Chi Minh City, said her studies showed that 81 infants out of 7,000 deliveries in the sprayed village of Thanh Phong were born with congenital birth defects. A similar number of births in Hanoi resulted in only 29 infants with birth defects, she said.

To determine whether the elevated rates of defects were caused by the dioxin in the herbicide Agent Orange, further research needs to be conducted, the scientists said.

Schecter, a professor of preventive medicine at the State University of New York, and the Vietnamese scientists said more studies are needed to determine whether the adverse health effects are directly related to the exposure to Agent Orange. Those studies should be conducted in Vietnam because that population was the largest exposed to the herbicide for the longest time, they said. Any conclusions there would help determine the health effects in American veterans who were exposed.

"Whether we are interested in helping these people or furthering scientific research, the populations do exist" to do the studies.

Although the levels of dioxin in the blood and fat tissue have decreased since the time of exposure, the scientists said that levels are still high enough to conduct studies on the populations sprayed or on the children who were nursed on contaminated milk and therefore still would be at risk for any toxic effects of the chemical.

Analyzing the dioxin levels in fat tissue requires a biopsy, or extraction of tissue, which can cost more than $2,000 per person, Schecter said. Fat tissues are better for measuring dioxin levels than blood samples, he said, because the dioxin is contained in lipids, which are more prevalent in fat than in blood.

But officials at the federal Centers for Disease Control in Atlanta dispute Schecter's claim. Scientists there concluded that blood samples were just as reliable as fat tissue samples for measuring concentrations of dioxin.

DEPARTMENT OF THE AIR FORCE
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235

25 AUG 1987

RECEIVED OCT 1 9 1987

Honorable Thomas Daschle
United States Senate
Washington DC 20510-0001

Dear Senator Daschle

In response to your recent letter concerning the Air Force epidemiologic study of the health effects of Agent Orange, Dr Joel Michalek, Dr Richard Albanese and I have prepared the following comments in response to your specific questions. Dr Albanese was a study principal investigator from 1978 to 1984. Dr Joel Michalek was a major study contributor from 1978 to 1984 and has been a principal investigator since, while I have served as principal investigator since 1978.

a. Reference your paragraph 1. Verification of all reported birth defects in the children fathered by the participants in our study was conducted using medical records and birth certificates in 1984. Sixty one percent of the defects reported by the Ranch Handers and their wives and 63% of those reported by the comparisons were verified as being codable defects. These percentages were not statistically different, and there is no evidence of differential reporting of these data. The Ranch Hand children had increased numbers of birth defects, but the increase was in those children born to mothers who smoked during pregnancy. There was no evidence of any association with herbicide exposure but such an association cannot be said to have been ruled out. A report of the analyses of these data was submitted to the Advisory Committee in 1984 but they recommended that it not be published. The verification of all reported birth defects has resolved one source of possible bias in the study of reproductive endpoints (overreporting). However, potential bias from underreporting remains. The negative reports on the remaining 5,614 children are currently being verified by medical record review. This is a very time-consuming process due to difficulties in locating and obtaining records. Many of these "children" are now adults and their consent must be obtained before records can be requested. I anticipate completion of this effort by November 1988. The verified data will then be analyzed and the results will be released after review by the Advisory Committee appointed by the Agent Orange Working Group.

b. Reference your paragraph 2. A series of flight tests was performed in C-123 aircraft in 1981 by Major Stephen L. Meek as background for a master's degree thesis at the University of Washington School of Public Health. The results of his work were considered in the development of the exposure assessments used in our data analyses. Unfortunately, technical difficulties were encountered in the conduct of the study, and the data were not as helpful in clarifying exposure as we all had hoped. Further preliminary work was conducted by the Air Force Occupational and Environmental Health Laboratory to assess the feasibility of using glycerin as a simulant. However, full-scale simulations were not conducted due to operational difficulties. Additionally, significant difficulties were encountered in developing scenarios that accurately reflect the actual in-flight conditions prevailing during the 9 years the combat missions were flown. The recent development of a technique to determine dioxin levels in serum will provide a direct measure of individual exposure without reliance on the assumptions and uncertainties implicit in simulation studies.

c. Reference your paragraph 3. In May 1984, Dr Bernadine Bulkley (formerly of the Office of Science and Technology Policy) asked that we verify several of the baseline report results. However, these verifications were already underway by our staff prior to her request. A meeting occurred with the staff of the Office of Science and Technology Policy in October 1986 to provide them with an update of the Air Force study. No technical direction was received at that time. They have acted as advocates of the program to obtain legislative support. The Air Force Surgeon General's office and the Air Force Systems Command (AFSC) headquarters have had no control over the science of the study. AFSC and intervening staff offices have managed funding and personnel resources, relieving the program scientists of these burdensome but important administrative tasks.

d. Reference your paragraph 4. The Advisory Committee for our study was appointed by the Agent Orange Working Group. The baseline report sent to the Advisory Committee was essentially the same as the published report. The committee recommended several editorial changes in writing style and emphasis but felt no additional data analyses were indicated. They felt the Executive Summary should be expanded, emphasis should be placed on an explanation of elements used in determining causality, and other minor "wordsmithing" changes should be made. The comments of the committee were included in the final report. The initial morbidity report contained "followup" analyses of data which, unfortunately, are subject to misinterpretation. This difficulty has been mitigated in the second morbidity report by strict adherence to a preset statistical protocol. Specifically, while the increment in Ranch Hand cancer appears limited to the skin, a systemic increase cannot be unambiguously ruled out. Similarly, the increased reported birth defect rate may not be confined to minor lesions.

e. Reference your paragraph 5. All interactions with the Advisory Committee have been purely technical in nature, dealing exclusively with epidemiologic and statistical issues. The concerns of veterans were foremost in the initial decisions in 1978 and 1979 to proceed with this study. Although a veterans' group representative was not on the committee, veterans' concerns are addressed. We are committed to caring for the Air Force community, including retired and separated Air Force veterans. Their welfare is our first priority.

f. Reference your paragraph 6. The Australian, Centers for Disease Control (CDC), and Air Force studies are relatively consistent in their conclusions. However, while they do not assert a causal relationship between Agent Orange and adverse health, a clear exoneration of the defoliant and its dioxin contaminant is not supported. All of these studies, including the Air Force-sponsored research, suffer from some limitations. The studies have been limited in their ability to accurately measure individual levels of exposure to the chemicals, and a more precise estimation of exposure is needed before definitive conclusions can be made. The CDC birth defect and Air Force studies are the only ones specifically addressing Agent Orange with dioxin exposure. The others are limited to the effects of Vietnam service, and the findings cannot be interpreted as the result of Agent Orange. All of these studies suffer from misclassification of exposure. The opportunity to make more accurate exposure assessments in our study is available with the serum dioxin assay. Design problems in the CDC and the Australian birth defect studies were apparent in their inability to control for the pre-Vietnam reproductive experience of the study groups. Similarly, the lack of medical verification of the birth certificate data is a significant weakness in these studies. Due to the small number of deaths occurring to date in these relatively young populations, all of the mortality studies suffer from low statistical power to detect increases in important disease categories. Despite their limitations, these six studies have been conducted as carefully and as scientifically as possible, and they have made major contributions toward the clarification of the Agent Orange/dioxin controversy.

g. Reference your paragraph 7. The weight of scientific evidence from epidemiologic studies in humans does not confirm a link between Agent Orange and adverse health nor does it rule out such a link. Continued surveillance is definitely indicated. Latency periods for malignant disease are just being reached, and studies have identified several findings which need to be reevaluated in subsequent examinations to determine their clinical relevance. At this time, Agent Orange cannot be implicated or exonerated.

h. Reference your paragraph 8. Additional work in establishing exposure through the use of the serum dioxin assay is needed. This assay will reduce uncertainties in estimating individual exposures and will significantly decrease any misclassification in the analysis of the data from the Air Force study. We are currently working with the CDC to implement this procedure for the analysis of the 1987 physical examination data. This procedure will improve our exposure assessments and should support more solid statistical and epidemiologic conclusions if it is applied to all participants, including the comparisons. In the context of the Air Force study, the dioxin assay presents a unique opportunity to clarify the dioxin issue.

i. Reference paragraph 9. The principal investigators in the Epidemiology Division have full and final responsibility for the science of the study. The Advisory Committee has scientific oversight of the study and works closely with the Air Force team. The Air Force management structure limits its impact on the study to purely administrative matters of funding, manpower and equipment management. In October 1984, the Commander of the USAF School of Aerospace Medicine resolved an impasse among the principal investigators concerning the format of the 1984 Mortality Report. It was later very clear that his solution was scientifically correct. All reports are released by the Air Force Surgeon General in the form approved by the Advisory Committee. The report of the 1985 physical examinations is currently being prepared for review by the Advisory Committee, and public release is expected in the fall of this year. Similarly, the 1987 update of the ongoing mortality study is expected in January or February 1988.

j. Reference your paragraph 10. The principal investigators have attended scientific meetings in this and other countries to freely exchange information on the Agent Orange/dioxin issue. Telephone and mail contacts are equally unrestricted. For a time after the release of the first morbidity report in February 1984, all public inquiries were coordinated through the Public Affairs Office; all questions were answered by designated individuals.

I hope this material is of assistance to you and your staff.

Sincerely

William H. Wolfe

WILLIAM H. WOLFE, Colonel, USAF, MC
Chief, Epidemiology Division

MILITARY ORDER OF THE PURPLE HEART
CHARTERED BY CONGRESS

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OFFICE OF National Service Director

January 6, 1988

RECEIVED JAN 1 1 1987

The Honorable Thomas A. Daschle
SH-317 Hart Senate Office Building
Washington, DC 20510

Dear Senator Daschle:

Thank you for your letter of December 17, 1987, regarding "S. 1787", a bill to amend title 38, United States Code, to prescribe certain presumptions in the case of veterans who performed active service in Vietnam during the Vietnam era. Also, the seeking of the Military Order of the Purple Heart's endorsement of "S. 1787".

Your request has been reviewed with our National Commander, Donald M. Skinder, and he has directed that the Military Order of the Purple Heart support the concept of S. 1787.

For years now, the Military Order of the Purple Heart has monitored and participated, to a degree, with those responsible for conducting the various scientific studies mandated/directed by the US Congress and other governmental agencies as well as state government, and quasi-private efforts to determine if the toxic effects of dioxin/Agent Orange does in fact have a causal effect upon the physical/psychological processes of the human body. To date, there continues a difference of opinion, and no irrefutable, scientific evidence to sustain a specific position has been forthcoming.

We do know that there are many Vietnam Veterans who do believe that their ailments -- physical/psychological -- were caused by exposure to Agent Orange or other herbicides that were used in the Republic of Vietman.

It is hoped that a definitive scientific determination of the causal effects of Agent Orange can be achieved before the Vietnam Veterans have all expired. However, while the scientific studies continue, medical treatment for ailments determined as possible effects from exposure to the various herbicides or as a result of the total vietnam experience should be provided by the Veterans Administration.

At our 55th Annual National Convention the following resolution was passed by the convention body:

RE: HERBICIDE EXPOSURE - AGENT ORANGE

WHEREAS: Herbicides, the most common known as "Agent Orange", were utilized in great quantities in Vietnam; and

WHEREAS: Many Vietnam Veterans were exposed in varying degrees to these toxic defoliants; and

WHEREAS: The Military Order of the Purple Heart is on record supporting the premise that exposure to herbicides may cause certain health defects; and

WHEREAS: The Center for Disease Control has been contracted by Congress to conduct studies into the health effects of herbicides on Vietnam Veterans. We believe the Vietnam Veterans should be given benefit of doubt in the prosecution of their claims until this study is completed; now, therefore, be it

RESOLVED: By the Military Order of the Purple Heart of the United States of America, that we continue to endorse and support liberalizing criteria for disposition of herbicide related claims, to include placing the burden of proof for the award of disability compensation on the U.S. Government rather than on the veteran.

Respectfully request that you include this letter as a part of the record during the forthcoming hearing on S. 1787.

Yours in Patriotism,

Richard J. Gallant

Richard J. Gallant
National Service Director

RJG/bea

STATEMENT OF THOMAS E. HARVEY

DEPUTY ADMINISTRATOR OF THE VETERANS ADMINISTRATION

BEFORE THE

SENATE COMMITTEE ON VETERANS' AFFAIRS

MAY 12, 1988

It is a pleasure to be here to provide you with an overview of the Veterans Administration's activities regarding Agent Orange and our views on S. 1692 and S. 1787.

First, a quick overview. Progress has been achieved in our continuing search for answers and the results that have been obtained thus far are indeed encouraging. In summary, there appears to be a growing scientific consensus that soft tissue sarcomas are not associated with exposure to 2,3,7,8-TCDD, or dioxin, the contaminant of Agent Orange, nor with military service in Vietnam. There is also appearing a consensus that Vietnam veterans are not at increased risk for fathering children with birth defects. The Agent Orange Registry, which now has the results of more than 220,000 physical examinations of Vietnam veterans, still does not show any unusual health patterns among the Vietnam veterans who participated in the registry program. The results of the Air Force's Ranch Hand study which have been released thus far are also encouraging. Those men do not appear to be suffering from any unusual morbidity or mortality patterns. To be sure, there are still some troubling issues that must continue to be examined. Principal among these is the issue of whether non-Hodgkin's lymphoma is associated with exposure to Agent Orange or perhaps with service in Vietnam. Let me now, in more detail, discuss with you the significant research results that I have briefly outlined.

Soft Tissue Sarcomas Studies

In October 1987, the results of the VA/AFIP study entitled "Soft Tissue Sarcoma and Military Service in Vietnam: A Case-Control Study" were published in the Journal of the National Cancer Institute. This case-control study was concerned with men who were of draftable age during the Vietnam conflict and examined the association of soft tissue sarcomas with military service in Vietnam as well with as other host and environmental risk factors. A total of 217 cases of soft tissue sarcomas selected from the Armed Forces Institute of Pathology (AFIP) were compared to 599 controls for Vietnam service, occupational and non-occupational exposure to various chemicals, occupational history, medical history, and life style, for example smoking history and alcohol and coffee consumption. The results of the study indicate that Vietnam veterans, in general, did not have an increased risk of soft tissue sarcomas when compared to those men who had never been in Vietnam. Subgroups of Vietnam veterans who had higher estimated opportunities for Agent Orange exposure seemed to be at greater risk of developing soft tissue sarcomas when their counterparts in Vietnam were taken as a reference group. However, this risk was not statistically significant.

Also, as I will discuss later, the reliance upon military records as an indicator of exposure may now be challenged in light of the results of the TCDD validation study conducted by the Centers for Disease Control.

In a parallel study, the Agent Orange Projects Office, in collaboration with the VA's Pathology Service and the Armed Forces Institute of Pathology (AFIP) reviewed soft tissue sarcoma cases among Vietnam era veterans who had been admitted to VA medical centers during the period 1969 to 1983. The anatomic site, histopathology and relative frequency of soft tissue sarcomas were compared between Vietnam veterans and non-Vietnam veterans. The results of this research show that service in Vietnam had not increased the risk of developing this type of cancer. The findings of the study were published in the Journal of Occupational Medicine in December 1986.

Retrospective Study of Dioxins and Furans in Adipose Tissue

Since 1970, the Environmental Protection Agency (EPA) has been collecting adipose tissue for the monitoring of selected pesticides and since 1983 has been involved in a cooperative research endeavor with the VA to determine the levels of residues of dioxin in the general population. A detailed analysis of tissue specimens from approximately 250 men of the Vietnam era age group is underway. The specimens are being analyzed for 2,3,7,8-TCDD and several other related dioxins and furans to determine if service in the military, especially service in Vietnam, has resulted in increased levels of these compounds as compared to the concentrations in non-veterans of the same age group.

Vietnam Veterans Mortality Study

The results of the VA's "Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War" were released in September 1987. Patterns of mortality among 24,235 Army and Marine Corps Vietnam veterans were compared with that of 25,685 non-Vietnam veterans using standardized proportionate mortality ratios. The veterans were a random sample of deceased Vietnam era veterans identified in a VA computerized benefits file. Military service information was obtained from military personnel records, and cause of death information from death certificates. Statistically significant excess deaths were observed among Army Vietnam veterans for motor vehicle accidents, non-motor vehicle accidents and accidental poisonings. Similar findings have been reported in other studies of Vietnam veterans, including one recently reported by the Centers for Disease Control. Suicides were not more prevalant among Vietnam veterans. Marine Corps, but not Army, Vietnam veterans appeared to have an increased mortality from lung cancer and non-Hodgkin's lymphoma. This study did not investigate possible etiologic factors for these malignancies.

Because there has been some misunderstanding about the release of this study and its proper interpretation, I should like to describe for you the circumstances leading to its acceptance for publication in the Journal of Occupational Medicine. In late 1986, data collection and analysis for the study were completed by the VA's Office of Environmental Epidemiology. The manuscript was submitted to the Journal of the American Medical Association (JAMA) on February 13, 1987. Following that it underwent peer review by scientists selected by JAMA. It should be noted in this regard that peer review is the commonly accepted review process used by the scientific community to assist in establishing the credibility and validity of the research. The process assists in confirming the appropriateness of the study's methodology and the accuracy of the analysis of the researchers. Research flaws are often discovered and corrected by this stringent review process. In light of the possible significance of the findings of the mortality study of a statistical increase in non-Hodgkin's lymphoma and lung cancer in Marine Corps Vietnam veterans who served in the I Corps of Vietnam, it was especially important that this study undergo such a review process prior to its general release.

Following an initial period of review the manuscript was returned to the VA for revision. The comments of the peer reviewers were considered by the investigators and revisions were made in the manuscript and an explanation was provided for not accepting other reviewers' comments. The revised manuscript was returned to JAMA in May 1987. Following a review of the revised manuscript, the VA was advised by JAMA that a decision of non-acceptance for publication had been made.

The mortality study manuscript was subsequently revised and submitted to the Journal of Occupational Medicine (JOM). JOM advised the VA that a peer review would be initiated by that journal. Shortly thereafter, the press learned elsewhere of the study and published a brief article on the results. On August 20, 1987, the manuscript was provided to the Veterans Advisory Committee on Environmental Hazards for scientific review and was discussed during its October 15-16, 1987, meeting. The manuscript was also provided to the Domestic Policy Council's Agent Orange Working Group on September 3, 1987. On November 3, the VA was advised that the manuscript had been accepted for publication by JOM. It is anticipated that the manuscript will be published this month.

Let me provide you with a summary of the comments made by the Science Panel of the Agent Orange Working Group and by the Veterans' Advisory Committee on Environmental Hazards.

The Science Panel found that the study was well executed but criticized the authors for not advising the necessary caution in interpreting the study's findings. The panel determined that this study could not be used to infer anything about the effects of exposure to Agent Orange and agreed with the authors that further work is needed to evaluate causative factors. In regard to the finding of lung cancer in Marine Corps Vietnam veterans, the panel noted that this had not been seen in other studies and that the absence of smoking histories made the interpretation of the data difficult. Finally, the panel believed that the small number of statistical departures from expected mortality could be the result of chance alone.

The Congressionally established Veterans' Advisory Committee on Environmental Hazards concluded that the study was well-designed and well-conducted. The Committee stated that it was their best scientific and professional judgment that the findings concerning the non-Hodgkin's lymphoma and lung cancer, while statistically significant, should be interpreted with caution and are not conclusive. Among the reasons given for this cautionary statement was that a proportionate mortality study by its very nature cannot resolve the question whether the observed results constitute a direct cause-and-effect relationship. A study such as this, the Committee noted, can only lead to the identification of issues requiring further study and analysis. With respect to the lung cancer finding, the Committee also noted the absence of any information about the smoking history of the study's subjects. The Committee recommended no changes in the VA's current guidelines governing the adjudication of claims based upon exposure to dioxin.

In accordance with these recommendations, the VA is conducting five follow-up studies to confirm or complement the findings of the mortality study. First, the VA is updating the mortality study by including an additional 11,000 Vietnam era veterans' deaths in the analysis. These deaths occurred between 1982 and 1984. They will give added statistical power and cases with longer latency periods to the study. This is important because some of the diseases that have been suggested as being associated with Agent Orange exposure or Vietnam service may take a long time to develop. For example, it generally takes as long as 20 years for certain cancers to manifest themselves if they are caused by exposure to environmental chemicals such as Agent Orange. Almost all necessary data have been collected for this analysis.

Second, a separate analysis is planned for Army Vietnam veterans who served in the I Corps area of Vietnam. This is an effort to determine whether the Army veterans who were stationed in the same geographic areas as the Marine Corps veterans experienced mortality patterns similar to the Marines. The U.S. Army and Joint Services Environmental Support Group is assisting the VA in researching Army unit locations in Vietnam for given time periods.

Third, given the widely accepted view of a causal relationship between smoking and lung cancer, a special effort was made to examine military medical records of Marines in the mortality study who died from lung cancer in an attempt to determine their smoking status. The records, however, were not helpful.

Fourth, the VA is reviewing the Patient Treatment File for non-Hodgkin's lymphoma and Hodgkin's disease among Vietnam era veterans who have been treated in VA medical centers. The cases and the control patients will be compared with respect to service in Vietnam and other military service factors. The hypothesis is that if military service in Vietnam is not associated with an increased risk of non-Hodgkin's lymphoma or Hodgkin's disease, then the proportion of veterans having served in Vietnam or having certain military characteristics should be similar for both the cases and the controls.

Finally, a separate mortality study has been designed exclusively for Marine Corps Vietnam veterans. To date, the only study providing an overall mortality rate of the Vietnam veterans is a cohort mortality study recently published by the Centers for Disease Control, but it was restricted to Army veterans. A substantial portion (approximately 20%) of U.S. ground troops in Vietnam were Marines. Unlike the Army units, the Marine Corps units were located in one geographic area, I Corps. In view of the VA mortality study results and the lack of overall mortality rates as well as cause-specific mortality rates for Marine Vietnam veterans, a separate mortality study for Marine veterans will be conducted. The Marine Corps is cooperating fully with the VA in this effort.

Vietnam Veterans Epidemiological Studies - Pub. L. 96-151

As you will recall, Public Law 96-151 mandated that an epidemiological study be performed to determine the effects, if any, of exposure to dioxin. This was amended by Public Law 97-72 to include other possible causes of adverse health effects. In 1983, pursuant to an interagency agreement with the VA, the Centers for Disease Control (CDC) proposed three studies: the Vietnam Experience Study, designed to evaluate the overall impact of military service on Vietnam veterans; the Selected Cancers Study, designed to determine the risks of developing certain types of cancer among Vietnam veterans; and the Agent Orange Exposure Study, intended to assess possible adverse health effects on Vietnam veterans of exposure to the herbicide.

The Vietnam Experience Study is completed and the Selected Cancers Study is proceeding. The Vietnam Experience Study has looked at the health experience of Vietnam and Vietnam era veterans to determine whether Vietnam veterans have health problems different from those who did not serve in Vietnam. In February 1987, the CDC published the findings of a subset of the Vietnam Experience Study. Findings of this study, entitled

"Postservice Mortality Among Vietnam Veterans," indicated that although Vietnam veterans were found to experience a higher rate of postservice mortality than veterans who served elsewhere, this excess of deaths was due primarily to external causes, in other words, to motor vehicle accidents, suicides, homicides, etc. This pattern was similar to the increased mortality patterns due to external causes experienced among World War II and Korean combat veterans.

The Selected Cancers Study is focusing on whether Vietnam veterans are at increased risk of developing certain cancers which have been identified in the scientific literature as possibly associated with exposure to phenoxy herbicides and their dioxin contaminant. The cancers are: lymphoma, soft tissue sarcoma, nasal and naso-pharyngeal cancer, and primary liver cancer. The CDC reports that results from that study will be published in 1990.

With respect to the Agent Orange Exposure Study, I must report that this study cannot be done. Since 1980, the Veterans Administration, other Federal agencies, and contractors have attempted to design a satisfactory epidemiological study in fulfillment of the mandate to study the effects of exposure to Agent Orange. The difficulty is and has always been the inability to discriminate between exposed and unexposed ground troops. A variety of methods were employed in trying to address this problem. None of these attempts has been successful for several reasons:

(1) Military records lack sufficient detail to locate accurately an individual with respect to an area of Agent Orange usage with the exception of those men in the Air Force unit called Ranch Hand, men who directly handled the herbicide in preparing for and in flying aircraft runs to spray it. They are being studied carefully and repeatedly by the Air Force in a continuing research effort. The Congressional Office of Technology Assessment and the Science Panel of the Agent Orange Working Group have agreed that military records cannot be used as a basis for determining individual exposure.

(2) Self-reporting by Vietnam veterans of exposure cannot be used because troops were exposed to a variety of aerial sprayings thereby making it impossible for an individual to discriminate among the sprayings of Agent Orange, other herbicides, and insecticides.

The inability to evaluate exposure by other means led to a decision to use measurements of retained TCDD as a means of identifying exposure. TCDD (2,3,7,8-TCDD), a contaminant of Agent Orange, is retained in body fats after exposure to the herbicide and can be detected in the fats found in blood as well as in other body fats. Technical advances in assay techniques have made it possible to measure minute amounts of TCDD in human blood. The CDC utilized the technique to determine that the chemical persists in elevated amounts among individuals who were exposed to Agent Orange as Ranch Hand personnel and a group of persons exposed to TCDD in Missouri or in chemical plants.

The CDC has determined the TCDD content of blood from 646 Vietnam ground troop veterans and 97 "non-Vietnam" veterans matched to their contemporaries who had served in that country. The results demonstrated that the TCDD content was essentially the same whether a man was in Vietnam as a ground combatant or was never in that country. It was thus impossible to use the blood content of TCDD to identify a group or cohort of Vietnam ground troop veterans who had been exposed to Agent Orange.

In contrast to the ground troops, Air Force veterans of the Ranch Hand operation had blood content of TCDD that was several fold greater. There was, however, considerable variation from one Ranch Hand veteran to another. It thus is obvious that exceptional exposure to Agent Orange as long as twenty years ago would be detected in ground troops had it occurred. The CDC tells us that the so-called half-life (i.e., the period in which 50 percent of the chemical is eliminated through disintegration) of TCDD in humans is about 7 years which means that even a small excess 20 years ago would be detected today. These results make it exceedingly unlikely that any method will satisfactorily distinguish between exposed and unexposed Vietnam veterans. Therefore, a scientifically meaningful epidemiological study of the possible health effects of Agent Orange cannot be conducted.

Related Activities

Public law 96-151 required the Administrator to conduct a comprehensive review and analysis of the world-wide scientific literature relating to possible adverse health effects from exposure to the phenoxy herbicides or dioxins. In 1981, the VA published a two-volume Review of Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins. Because of continued active research, a two-volume update covering the literature through December 1983 was published in 1984. Each year since that time the review has been updated. Volumes Eleven and Twelve are now in publication. Lay language synopses have also been prepared on volumes one through ten of these publications for review and use by the general public.

These publications are routinely shared by the VA with Congress, all major VA health facilities' Environmental Physicians and hospital libraries, VA Regional Offices, the VA's Advisory Committee on the Health Related Effects of Herbicides, the Veterans' Advisory Committee on Environmental Hazards, the Domestic Policy Council's Agent Orange Working Group and its science panel, and with the governments of Australia, Italy, and New Zealand. Copies are also made available to veterans, State Agent Orange programs, and the general public upon request.

The VA continues to offer concerned Vietnam veterans a comprehensive physical examination as part of its Agent Orange Registry program. Approximately 228,000 Vietnam veterans have received examinations. Additionally, Vietnam veterans continue to be eligible for health care under the authority of Public Law 97-72 for any condition that may have been caused by exposure to dioxin or to a toxic substance in a herbicide or defoliant used in Vietnam.

Public Law 98-542, the "Veterans Dioxin and Radiation Exposure Compensation Standards Act," required the VA to specify standards for deciding compensation claims based upon exposure to Agent Orange or to ionizing radiation from participation in the nuclear weapons testing program or as a result of service with the occupation forces of Hiroshima or Nagasaki, Japan. The Act also required that a new Veterans' Advisory Committee on Environmental Hazards be created and consist of four lay members and eleven scientific members. The Committee reviews the scientific literature and provides comments and recommendations to the Administrator concerning administrative and legislative initiatives.

In August 1985, following a period of public comments and consultation with the Advisory Committee on Environmental Hazards, the VA published final regulations for the adjudication of claims based upon exposure to Agent Orange (and to ionizing radiation). Under the regulations, which also contain criteria the Agency will employ in evaluating scientific studies, chloracne, a skin disorder, will be presumptively service-connected if manifested within three months of the veteran's departure from Vietnam. The Agency also specifically found that sound scientific and medical evidence does not establish a cause and effect relationship between dioxin exposure and porphyria cutanea tarda (a liver disorder), soft tissue sarcoma, or any other disease except chloracne. Continued review of the medical and scientific evidence by the Advisory Committee has led it to maintain the same position.

VA's Views on Legislative Proposals

You had asked for the views of the Veterans Administration on two bills, S. 1692 and S. 1787. S. 1692 would provide a rebuttable presumption of service connection for non-Hodgkin's lymphoma for any Vietnam veteran provided a claim is received before September 30, 1991. The presumption may be rebutted by an affirmative showing that the disease was caused by some known agent subsequent to the veteran's departure from Vietnam or by a determination by the Administrator that the veteran was not exposed to herbicides while in Vietnam. S. 1787 would irrebuttably presume service connection for any Vietnam veteran who subsequently developed non-Hodgkin's lymphoma, lung cancer developing within 25 years after the veteran's departure from Vietnam, or immune deficiency disease determined to be reasonably associated with exposure to dioxin or to any other toxic herbicide in Vietnam. With respect to the diseases associated with the immunosupressive effects of herbicide exposure, a survey of the literature would be undertaken pursuant to a contract with a non-profit private scientific organization, preferably the National Academy of Sciences, which would provide a report containing the names of those diseases reasonably associated with damage to or suppression of the human immune system resulting from exposure to herbicides. This report would be up-dated on an annual basis. The Administrator would also be directed to provide a report on the clinical data obtained in connection with physical examinations and treatment furnished by the VA after November 3, 1981. The report, to be prepared semi-annually, would contain a summary of the information obtained, an analysis of that information, and an explanation for the incidence of such disabilities identified.

We strongly believe that presumptive service connection is not needed for any condition which can be shown by scientific evidence to have a cause and effect relationship with the circumstances of military service. Basic law and regulations regarding service connection would mandate direct service connection in such cases. We do not believe that it is sound public policy to make a sweeping presumption based on frustration or the lack of scientific evidence to support desired conclusions.

Addressing the disabilities listed as being presumptively associated with Vietnam service, non-Hodgkin's lymphoma and lung cancer, there is currently no scientific consensus that would sustain such an association. Studies that suggest an association with exposure to phenoxy herbicides involve population groups other than Vietnam veterans and must be interpreted with caution when attempting to apply their results to the Vietnam veterans' experience. The circumstances of the exposures were radically different for those involved with occupational spraying over long periods of time than those experienced by Vietnam veterans. In fact, the recently completed dioxin serum assay conducted by the CDC strongly suggests that Vietnam veterans did not have significant opportunities for substantial exposures to Agent Orange, as demonstrated by the lack of significant differences in dioxin content among those who served in Vietnam and those who did not.

Concerning the immune deficiency diseases, there is no evidence demonstrating that a cause and effect relationship may exist between exposure and subsequent harm to the immune system in humans. In this regard, S. 1787 calls for the National Academy of Sciences or some similar non profit scientific organization to conduct a literature survey on this question. Such a literature search would be duplicative of that already conducted by the VA. As I reported earlier, the VA has issued 10 volumes of literature search and analysis on the effects of exposure to herbicides since 1981, and volumes 11 and 12 are in production. These highly regarded volumes have proven to be a valuable resource. A review of those volumes fails to reveal any indication that exposure to phenoxy herbicides can result in permanent impairment of the immune response. Furthermore, the Congressionally established Veterans' Advisory Committee on Environmental Hazards monitors the scientific literature, performing an evaluative function like that proposed in the bill for the National Academy of Sciences.

Finally, concerning the requirement that the VA monitor and report on the clinical data obtained from physical examinations and treatment funished after November 3, 1981, the value of such a report would be quite limited. The data sought to be analyzed is that generated by Vietnam veterans seeking health care from the VA. The VA currently monitors these data as well as those generated by the Agent Orange Registry program. We have repeatedly cautioned against over-interpretation of this data primarily because it may not be representative of the Vietnam veteran population. It is only descriptive of those self-selected individuals who for a variety of reasons sought either health care or a physical examination from the VA.

Conclusion

In conclusion, I would like to emphasize that the Veterans Administration has addressed the Agent Orange controversy forthrightly and aggressively. The long-awaited research results are now becoming available, and the parts of the Agent Orange puzzle are begining to present a clear picture. Some preliminary conclusions are encouraging. Based upon the currently available information, it appears that Vietnam veterans did not have substantial opportunity for significant exposure to Agent Orange. Careful studies have failed to detect any relation between birth defects in children and Vietnam service or exposure of fathers to the components of Agent Orange.

Evidence for an association between exposures to phenoxy herbicides, including Agent Orange, or the contaminant 2,3,7,8-TCDD and malignancies remains conflicting. Recent evidence strongly suggests that soft tissue sarcomas are not causally related to exposure to phenoxy herbicides or military service in Vietnam. Recent evidence regarding a causal association between herbicide exposure and non-Hodgkin's lymphoma is inconclusive. Further work is being done on this issue. The growing and mounting scientific evidence does not support any change in compensation policy at this time. While the pieces of the puzzle continue to come into focus, we will continue to offer medical care and services under the authority of Public Law 97-72 to eligible Vietnam veterans for those conditions that may possibly be related to exposure to Agent Orange notwithstanding the absence of any scientific evidence of a causal association. That is an obligation which we shall strive to meet with compassion and understanding. Our Vietnam veterans deserve no less.

PROPOSAL FOR VETERANS ADMINISTRATION ENVIRONMENTAL MEDICINE OFFICE

(Subject to Approval by the Administrator
of Veterans Affairs)

PROPOSAL:

The Veterans Administration's (VA) Department of Medicine and Surgery (DM&S) proposes to expand the functions of the present Agent Orange Projects Office to include the responsibility of oversight and management of radiation-related medical issues of concern to veterans exposed to radiation from participation in nuclear weapons testing or as a result of service with the occupation forces of Hiroshima and Nagasaki, Japan. The expansion would subsequently include the addition of program responsibilities related to the medical management and oversight of occupational hazards of concern to VA medical facility employees, patients, and visitors (e.g., hospital hazards such as ethylene oxide, asbestos, etc). This expansion of functions will result in the redesignation of the Agent Orange Projects Office (AOPO) as the Environmental Medicine Office (EMO).

CURRENT ORGANIZATION/PROGRAM ACTIVITIES:

Currently, the AOPO serves as the focal point within DM&S for the coordination of research and non-research related efforts essential to the ultimate resolution of the health issues raised by the use of the defoliant, Agent Orange. These responsibilities include, among others, the following major program functions: oversight and management of epidemiological and other research conducted by the VA's Office of Environmental Epidemiology (OEE); monitoring and financial support of the major epidemiological study authorized by Public Law 96-151 and as expanded by Public Law 97-72 (this activity includes the mandated responsibility to report on an annual basis to Congress the status of this major research effort) coordination of activities of the VA's computerized Agent Orange Registry program of special physical examinations for concerned Vietnam veterans; monitoring and reporting of status of the health care delivery system for Vietnam veterans as authorized by Public Law 97-72; preparation of an annual update of the scientific literature on herbicides including phenoxy herbicides and dioxins (includes preparation of lay language synopses of these publications for the general public); preparation of monographs on various program related issues for the education of VA health care professionals and others; management of the VA's Advisory Committee on Health-Related Effects of Herbicides; participation in activities of the Domestic Policy Council's Agent Orange Working Group (AOWG) and of its Science Panel; preparation and participation in congressional hearings on Agent Orange; monitoring and interface with the various State Agent Orange commissions/committees; preparation of Agent Orange-related films for the training of VA health care and Medical Administration Service staff; provide assistance in the development and distribution of Agent Orange Reviews to provide Vietnam veterans and the general public with information on the status of VA Agent Orange-related efforts; interface with various foreign governments on Agent Orange issues including among others the governments of Australia, Canada, and Italy; and finally, the conduct of routine administrative activities associated with the maintenance of the program.

PHASED REORGANIZATION/STAFFING PLANS:

The VA's proposal for reorganization of the AOPO to include radiation and hospital hazards would require the eventual expansion of the office's 8.0 FTEE to 11.0 FTEE. The addition of these staff members would be keyed to the level of program responsibilities which will be assumed on a phased-in basis during the year or more following reorganization. The present staffing of the AOPO is adequate to meet its currently assigned program responsibilities, however, it is recognized that the gradual assumption of radiation-related and hospital hazards efforts would require the addition of specialized staff and resources, as required, to meet the demand of the increased workload (attachment). The current Director of the AOPO would serve as Director of the Environmental Medicine Office. The individual occupying this position has extensive professional training and experience in dealing with both Agent Orange, radiation and other environmental issues. The expansion of the AOPO to include radiation and hospital hazard responsibilities would impact on the need to expand the staffing level of the OEE which is currently responsible for the conduct and monitoring of Agent Orange-related research. Radiation and other research needs would require an additional 3.0 FTEE for a total of 14.0 FTEE for that program.

RADIATION-RELATED PROGRAM ACTIVITIES:

The radiation-related administrative and other research/non-research program responsibilities of the EMO would parallel, in most respects, those of the AOPO. The EMO would assume responsibility for research regarding the health effects of radiation, the organization and eventual activation of an ionizing radiation register, continuing review of information and scientific opinion on the issues, representation of the VA in such matters, and other related activities. The functions of this office will be closely coordinated with other internal VA programs including, among others, Clinical Affairs, Occupational Safety and Health and the DM&S Building Management Service. Interface with other Federal and private sector agencies/organizations will be required. Ultimately, the office may expand the functions of the VA medical center environmental physicians, those individuals presently responsible for the medical oversight of Agent Orange and radiation examinations and the delivery of health care in the field, to include local coordination of radiation-related examinations and health care services for eligible veterans. Similar activities would be required for the management and coordination of hospital hazards.

SUMMARY:

Historically, issues related to radiation have been managed by the DM&S's Nuclear Medicine Office which is now decentralized to a VA health care facility. The reorganization of the AOPO as the EMO will provide a central and logical point within central office to handle two major environmental issues and various hospital-related occupational hazards. The present staff and organization of the AOPO will form the nucleus of a program which can meet the unique needs of veterans concerned about the possible adverse health effects of their possible exposure to Agent Orange and/or radiation and would also, assist in the management of issues of concern to VA employees. The planned phase-in of the new program responsibilities will ensure no lessening of effort or resources to be spent on each program issue.

Assuming no unforeseeable barriers to the planned reorganization, the VA is prepared to proceed with the proposed establishment of the EMO with the dual program responsibilities as described.

PROJECTIONS FOR ENVIRONMENTAL MEDICINE OFFICE (EMO)

Current Staffing/Budget:	Staffing Level	(Annual) Est. Staffing	(Annual) Est. Research*	Duration
	(FTEE)	Funding	Funding	(After FY 1988)
(Agent Orange Only)				
AOPO (Agent Orange Projects Office VA Central Office)	8.0 (MAMOE)	$300,000	$2,625,000 (CDC)	0 Months
OEE (Off. of Env. Epidemiology Washington VA Medical Center)	11.0 (R&D)	$450,000	$1,000,000	
Projected Staffing/Budget:				
(Agent Orange & Radiation)				
A. EMO (Env. Medicine Office)	8.0 (MAMOE)	300,000	2,725,000 (CDC)	12 Months
OEE	11.0 (R&D)	450,000	1,000,000	
B. EMO (1)	9.0 (MAMOE)	326,000	2,725,000 (CDC)	6 Months
OEE (2)	12.0 (R&D)	471,000	1,000,000	
(Agent Orange/Radiation /Hospital Hazards)				
A. EMO (3)	10.0 (MAMOE)	364,000	740,000 (CDC)	6 Months
OEE (4)	14.0 (R&D)	523,000	1,000,000	
B. EMO (5)	11.0 (MAMOE)	402,000	0	Continuing
OEE	14.0 (R&D)	523,000	1,000,000	

(1) One additional	Management Analyst	(GS 9-11)
(2) " "	Statistician	(GS 7-8)
(3) " "	Program Analyst	(GS 12-13)
(4) " "	Statistician	(GS 11-12)
" "	Secretary/typing	(GS 6-7)
(5) " "	Technician	(GS 12-13)

Note:

*Dollars to support research reflect estimated funding for Agent Orange/Radiation and other research as required (e.g., asbestos, ethylene oxide, etc.) Approximately $1 million annually for such research including current $2.625 million in funding for conduct of CDC epidemiology study in FY 1988, $2,750 million in FY 1989 and $740,000 in FY 1990.

.Research personnel within OEE are currently funded through Washington VAMC utilizing R&D 823 program account.
.Technical staff for EMO to be occupational hygienists or other equivalent personnel.
.All funding estimates, research and MAMOE, are based on FY 1988 dollars.
.AOPO funding does not reflect approximately $110,000 annually for literature review update or $5,300 (+/-) travel dollars for AOPO $5,000 for OEE).

VETERANS ADMINISTRATION
1930

The Deputy Administrator
of Veterans Affairs
Washington, D.C. 20420

AUG 2 [illegible] 1988

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed are copies of letters to Senator Kerry and Senator Daschle responding to statements made by them in connection with the Committee's May 12, 1988, hearing on Agent Orange. I am requesting that these letters be made a part of the record for that hearing.

Sincerely,

Thomas E. Harvey

THOMAS E. HARVEY
Deputy Administrator

Enclosures

"America is #1—Thanks to our Veterans"

JUL 1 8 1988

Honorable John Kerry
United States Senate
Washington, D.C. 20510

Dear Senator Kerry:

At the recent hearings before the Senate Veterans Affairs' Committee on Agent Orange, you referred to a number of studies which you believe set forth a basis for concluding that compensation is warranted for Vietnam veterans exposed to Agent Orange. I asked my staff to review the materials you referred to in order to ensure that we had not missed something in our analysis of the literature. I am enclosing the results of their review.

Quite frankly, it presents an entirely different picture from the one portrayed in your statement. Far from conclusively demonstrating that Vietnam veterans are experiencing unusual health problems, the various studies you referred to tend, instead, to demonstrate that Vietnam veterans are not at increased risk for adverse health. Some of the studies do raise questions which must be pursued. And we are pursuing them.

The Veterans Administration has tried to assess the scientific literature impartially and to report accurately its content. Only by this approach, can a conclusion based upon sound science be fairly arrived at. Our search for answers to the elusive issues raised by Agent Orange will continue until this goal is achieved.

Sincerely,

THOMAS E. HARVEY
Deputy Administrator

Enclosure

The Deputy Administrator
of Veterans Affairs
Washington, D.C. 20420

AUG 22 1988

Honorable Thomas A. Daschle
United States Senate
Washington, D.C. 20510

Dear Senator Daschle:

Following the May 12, 1988, hearing on the status of scientific information concerning the effects of exposure to Agent Orange, you provided additional information for the hearing record. That information appeared in the May 26, 1988, edition of the Congressional Record. I asked staff at the Veterans Administration to review the additional information you provided and am happy to share that analysis with you.

You had expressed in your remarks disagreement with my assessment concerning the absence of a causal association between exposure to dioxin and alteration of the immune system. You made reference to the testimony of Dr. Thomas Gasiewicz and to volume IX of the VA's Review of Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins.

Dr. Gasiewicz presented, in our judgment, a qualified viewpoint based in large measure upon unproven hypothesis. For example, he stated that "while effects...such as cancer development and alterations of immune functions have been suggested, these have not been conclusively demonstrated to occur in humans ...." (Emphasis in original.) He then went on to note the animal study findings of a relationship between exposure and effects on the immune system. He observed, "that since these findings are consistent in all experimental mammalian systems yet examined, it is reasonable to deduce that at some exposure level, similar toxic effects are likely to be seen in humans." Dr. Gasiewicz did not indicate what that exposure level might be. He then related certain animal findings and human tissue in vitro studies and concluded "it is logical ... that similar effects may occur in humans." (Emphasis added.) This is far from being an unequivocal statement based upon valid scientific study.

"America is #1—Thanks to our Veterans"

In volume IX of the VA's literature review, there appears a discussion of immunotoxicity. "Studies of humans exposed to phenoxy herbicides or chlorinated dibenzo-p-dioxins have not convincingly demonstrated any association between such exposures and impaired immune function." Since that volume was published, additional studies involving immune system response have become available. In one, residents of a mobile home park in Missouri where soil was contaminated with dioxin were retested. An earlier and unsatisfactory test had found that exposed residents were less likely to demonstrate a normal allergic response than the comparison group. On retesting, there was no difference in the response between the exposed people and the comparison group.

When immunological differences were looked for in the Ranch Hand study, no differences were seen between the Ranch Hand group and the comparison group by any measure of immune function. (See "Baseline Morbidity Study Results," February 1984; "First Followup Examination Results," October 1987; and "United States Air Force Personnel and Exposure to Herbicide Orange," USAFSAM-TR-88-3, February 1988.) In the Vietnam Experience Study, there were no significant differences in the results of the immune function tests between the cohorts. (See "Health Status of Vietnam Veterans: II, Physical Health." JAMA 259: 2708-2714, 1988.)

There is not, at present, any credible evidence that humans exposed to dioxin or to Agent Orange or any of its components suffer suppression of the immune system as a consequence of that exposure. What evidence there is is based upon animal models and in vitro analyses which are fraught with error when trying to extrapolate to human experience.

You also expressed criticism of the statement made by the Chairman of the Agent Orange Working Group and by a member of the Veterans' Advisory Committee on Environmental Hazards to the effect that studies to date of Vietnam veterans show no causal association between service in Vietnam and adverse health. The Veterans Administration fully supports that statement. The studies that have thus far been completed involving Vietnam veterans, not only of the United States but also of Australia, do not demonstrate that these veterans are experiencing unusual health problems. To be sure, there are some areas that have the potential for being a concern; for example, non-Hodgkin's lymphoma. Neither the VA nor any other Federal agency has ever tried to "oversimplify, downplay, or blatantly misrepresent scientific evidence" suggestive of a link between negative health effects and exposure to dioxin or service in Vietnam. Rather, the VA has consistently tried to place the various scientific studies into their proper perspective and to judge the significance of them on their own merits. It is interesting to observe that the American Medical Association, the government of Australia, and, indeed, the trial judge overseeing the settlement of the Agent Orange litigation have all commented at various times on the absence of any persuasive evidence of a causal association of exposure to the components of Agent Orange and subsequent adverse health.

You also made reference to the 1988 Air Force interim report and the 1987 Morbidity Followup results. You stated that these showed group differences in several important areas reasonably associated with dioxin in the literature, including cancers and birth defects. We are unaware of any study which reasonably demonstrates a cause and effect relationship between exposure to Agent Orange or to its components and subsequent adverse health, including the two sources you cited.

The interim report attempted to reanalyze the data from the 1984 Baseline Morbidity Study results in which the authors reported finding more skin cancer of borderline significance in the Ranch Hand group and no significant group differences for the occurrence of systemic cancer. The 1987 followup results showed no statistically significant differences in systemic neoplasms and a statistically higher rate of basal cell carcinoma among Ranch Handers, the relative risk of which appeared to be declining over time. It is our understanding that the data concerning reproductive outcomes is still undergoing analysis and will be the subject of a subsequent report. In any event, the 1988 interim report indicates only the theoretical possibility of unfavorable reproductive outcome following male exposure. No study conducted thus far has actually demonstrated such an effect, however.

With regard to the Vietnam Experience Study, you stated that "statistically significant findings seem to have been treated in a less than even-handed way, and there is an apparent desire to scrutinize the positive findings until they can be explained away." You then cite as an example the reported group difference in non-Hodgkin's lymphoma: six cases among Vietnam veterans as compared to one case in the comparison group. In a letter to the

Veterans' Affairs Committees, the Centers for Disease Control has provided additional information concerning these findings. First, an additional case of non-Hodgkin's lymphoma was reported for the Vietnam veterans group. Second, the CDC reports that the non-Hodgkin's lymphoma cases were not homogenous with regard to cell-type, two of the cases being an extremely rare type of lymphoma and thought to have a different origin from other non-Hodgkin's lymphomas. Third, one of the Vietnam cases was diagnosed while the veteran was still in Vietnam and the other two were diagnosed within three and four years of leaving Vietnam. It is doubtful that these three cases could be attributed to military service as it is generally accepted that environmentally related cancers have a longer latent period than was observed in these cases. The remaining four cases of non-Hodgkin's lymphoma, the CDC reports, are within the range of what might be expected for a young male group of this size, that is, 3.9 cases. Finally, the findings with respect to non-Hodgkin's lymphoma among Vietnam veterans are not consistent and the CDC notes that the VA's mortality study showed a deficit in non-Hodgkin's lymphoma mortality among Army Vietnam veterans. It is our opinion that this additional information allows for a more considered judgment about the significance of these findings and that it would have been irresponsible of the Centers for Disease Control not to have pursued the issue further rather than drawing what would now be seen to be incorrect conclusions.

In closing, let me again emphasize that the Veterans Administration is committed to pursuing this issue to wherever sound scientific research leads us and, on the basis of that scientific truth, to take whatever action may be necessary to serve the interests of the Vietnam veterans. It is my belief that that commitment has been more than amptly demonstrated by the actions of the Veterans Administration throughout the decade that the Agent Orange controversy has existed.

Sincerely,

THOMAS E. HARVEY
Deputy Administrator

1. "In 1983, the VA Agent Orange registry found excessive cancers among Vietnam veterans of two types - non-Hodgkin's lymphomas, and cancers of the oral cavity and pharynx."

This refers to a report on the Agent Orange Registry presented in 1983 at a meeting of the Environmental Chemistry Division of the American Chemical Society. A summary of that report was printed in September 11, 1983, edition of *Chemical and Engineering News*. The article correctly pointed out the limitations of the data contained in the Registry:

> The agent orange (sic) registry is a compilation of health information on Vietnam veterans who came to VA hospitals concerned about the effects exposure to agent orange and its dioxin contaminant might be having on their health. VA has not confirmed that the people in the registy actually were exposed to agent orange during their Vietnam service... *(Dr. Alvin) Young points out that since the registry is a self-selected group and people with health problems are more likely to consult a physician, such people are very likely to be overrepresented in the registry*. (emphasis added) Consequently, VA is careful not to call the registry an epidemiological study. It is merely a compilation of health information on a group of men who served in Vietnam.

The article also noted that there were two classes of cancer for which veterans in the Registry had a slight, but statistically significant increased incidence over the control group. (The "control group" was a comparable group of other U.S. males of the same age group.) The cancers were reported as "cancers of the buccal cavity and pharynx (with 7.9% of the tumors in the registry in this class compared with 4.5% in the control group) and lymphomas (20.0% in the registry compared with 15.0% in the control.)" The report does not distinquish between Hodgkin's disease and non-Hodgkin's lymphoma. It was further reported that Dr. Young stated it was too early to tell what those differences meant.

2. "A 1983 study by the Massachusetts Agent Orange Commission found excessive numbers of soft-tissue sarcomas and cancer of the kidney among Vietnam veterans exposed to Agent Orange."

We are not aware of a 1983 study which meets this description. There is a study by Kogan and Clapp, released in 1985, entitled, "Mortality Among Vietnam Veterans in Massachusetts, 1972-1983" which found an approximately nine-fold increased risk for connective tissue cancers and a slightly less than two-fold increased risk of kidney cancer when comparing Vietnam veterans to non-Vietnam veterans. There was also a moderately increased risk among Vietnam veterans of "estimated suicides" which included unknown causes of death and poisonings in addition to recorded suicides. Deaths from all external causes including motor vehicle accidents were also moderately increased. The authors commented, "This study is a first step in analyzing Vietnam veterans' experience of one particular health outcome (mortality). Therefore, it can be used only to draw very general conclusions and to develop hypotheses for further studies."

In addition, the authors of this study made the following observations regarding their findings:

> Previous studies have reported that soft-tissue sarcomas were associated with exposure to phenoxyacetic acids such as 2,4-D and 2,4,5-T, the components of Agent Orange. For all of the cases with the possible exception of case 9, occupational exposure as obtained from the death certificate, did not seem to be significant. A more recent study of upstate New York Vietnam veterans reported no excess of soft-tissue sarcomas diagnosed through 1980. The present study was not based on either adequate numbers of deaths, or adequate exposure information to help resolve this important issue. (Emphasis added.) Nevertheless, the highly significant excess of this rare malignancy in Vietnam veterans is important new information. The latency period for soft-tissue sarcoma in adults is probably sufficiently long that several more years of observation will be necessary before any conclusive findings can be made...Kidney cancer is less rare than soft-tissue sarcomas and was found to be significantly elevated in Vietnam veterans compared to non-veteran white males. Possible confounding due to cigarette smoking, analgesic use or other known risk factors among veterans should be considered, but information on those risk factors was unavailable in this study. Further studies may also shed light on this finding.

The increased risk of death due to suicide, motor vehicle accidents, and other external causes found in this study is consistent with data found in other studies of Vietnam veterans and studies of veterans who served in World War II and Korea. The Massachusetts study, however, did not provide information on the time periods these deaths occurred. This is important because the studies relating to combat veterans generally found similar increased risk for death due to external causes during the first 5 years following return from the combat theater. Other limitations of this study include the lack of confirmation of death certificate information (e.g., confirmation by a pathologist of the presence of soft-tissue sarcoma), the lack of validation of service in Vietnam, and the failure to address sources of bias (e.g., the effect of excluding Vietnam veterans who failed to apply for the bonus administered by the state for service in Vietnam).

3.

A final observation about the study is that because no attempt was made to analyze for Agent Orange exposure, no conclusions can be drawn with regard to the possible effects of such exposure.

3. "The 1984 Ranch Hand baseline study found higher amounts of skin cancers and systemic cancers, twice as many cancers of the lip, oral cavity and pharynx, and three times as many cancers of the respiratory system, chest, and genito-urinary system."

The authors of the 1984 report had concluded:

> (T)here is insufficient evidence to support a cause and effect relationship between herbicide exposure and adverse health in the Ranch Hand group at this time. The study has disclosed numerous medical findings, mostly of a minor or undetermined nature, that require detailed follow-up. In the full context, the baseline study results should be viewed as reassuring to the Ranch Handers and their families at this time.

The authors further stated:

> There are no significant group differences for malignant or benign systemic tumors. One case of soft-tissue sarcoma is noted in a member of the comparison group. A slight nonsignificant aggregation of genitourinary cancers is identified in the Ranch Hand group, and an aggregation of digestive system cancers is observed in the comparison group. Two Ranch Hand bladder cancers are noted at earlier-than-expected ages. A borderline association between systemic cancer and smoking is observed in both groups. Significantly more nonmelanotic skin cancer is observed and verified by medical record review in the Ranch Handers. The predominant cancer, basal cell carcinoma, is the most common skin cancer in the U.S. white male population, and a proper excision is curative. While this finding is of interest, it is emphasized that these data are not adjusted for sunlight exposure, the recognized primary cause of these cancers. This analysis must await more complete data to be collected at the first follow-up examination. Overall there is no consistent data to show that the Ranch Handers are developing uncommon systemic cancers, or cancer in unusual sites, or at a younger age. Both systemic and skin cancers in the Ranch Hand group do not correlate consistently with the herbicide exposure index.

4.

4. "A 1985 study in Wisconsin found excessive incidences of soft-tissue sarcomas among Vietnam veterans who had been exposed to Agent Orange."

In 1985, a three phase mortality study involving Wisconsin veterans was completed. Phase I used proportionate mortality ratios to compare the mortality experience of all Wisconsin veterans to Wisconsin non-veterans. There were no significant differences between veterans and non-veterans as to the causes of death with evidence of the "healthy veteran effect" and of effects from alcohol and tobacco use by veterans. Violent deaths from external causes and psychiatric disturbances were also relatively more common among veterans.

Phase II contrasted Wisconsin Vietnam veterans and non-Vietnam veterans, non-Vietnam era veterans and non-veterans. This proportionate mortality study demonstrated that veterans had excess deaths due to external causes (e.g. all accidents, motor vehicle accidents, suicides, etc.) when compared to non-veterans. This was construed as possibly indicating a stress mediated mortality risk shared by all veterans' groups. This phase also showed a healthy veteran effect when examining deaths due to diseases of the circulatory, respiratory, nervous, and sensory systems and allergic, endocrine, metabolic, and nutritional diseases. Veterans had deficit proportionate mortality ratios for these diseases when compared to non-veterans, i.e. a smaller proportion of Vietnam veterans died of these causes. Vietnam veterans demonstrated an elevated risk for pancreatic cancer compared to non-veterans. The authors observed that Vietnam veterans had the same risk for soft-tissue sarcomas when compared to non-veterans and non-Vietnam veterans but an increased risk when compared to all other veterans. The authors noted that these findings must be interpreted with caution because of the small numbers involved. Vietnam veterans were also found to have had an increase in all diseases of the genito-urinary system when compared to all other veterans.

Phase III utilized a standardized mortality ratio (SMR) approach. This study compared the proportions of causes of death of Wisconsin Vietnam veterans to a cohort of non-Vietnam veterans. The results of this effort were interpreted as showing a healthy veteran effect among Vietnam-era veterans but with Vietnam veterans consistently demonstrating less of a protective pattern for all causes of mortality when compared to non-Vietnam veterans. Vietnam veterans had a higher risk for suicides when compared to non-veterans and a higher mortality ratio for all external causes of death, all accidents, and motor vehicle accidents when compared to non-Vietnam veterans.

Two comments need to be made about the generally well-planned and well-conducted study. First, the authors relied too heavily upon the DD214 as the source of information concerning service in Vietnam.

5.

It is generally accepted that a review of a veteran's service record is necessary to confirm actual service in the country of Vietnam. Second, the study assumes that service in Vietnam represents exposure to Agent Orange, which is a highly questionable assumption for research purposes.

5. "A 1986 study in West Virginia found higher incidences of non-Hodgkin's lymphomas, and cancers of the testes, larynx, and respiratory system among Vietnam veterans."

The authors of this study, Holmes, et al., summarized their findings as follows:

> In general, the pattern of death among in-country (Vietnam) veterans from all causes, and within the subcategories of "accidents, poisoning, and violence" and "cardiovascular diseases," were similar to those observed for all veterans combined, and there were no substantial differences in the mortality patterns between in-country and era veterans for these categories. Among cancer deaths, however, there was strong statistical evidence to suggest that Hodgkins's disease, cancer of the testis, and soft tissue tumors were more common among veterans who served in Vietnam than among veterans who did not. These findings must be interpreted cautiously, however, since the expected proportions of site-specific cancer deaths for in-country veterans were derived from a relatively small number (74) of cancer deaths among era veterans and would therefore be subject to considerably large random fluctuations. (Emphasis added.) At the same time, the difference between the observed and expected numbers of soft tissue tumors among in-country veterans supports similar findings in a previous proportionate mortality study conducted by the Massachusetts Department of Public Health. Neither the Wisconsin study nor the New York study found significant differences between in-country and era veterans in the occurrence of soft tissue sarcomas. These studies, however, and the present one are limited by the absence of precise exposure data, unknown sizes of the candidate populations at risk, and insufficient follow-up time to account for latency from exposures that might have been unique to in-country veterans. Also, by including deaths from as early as 1968, the present study may have been biased against finding an excess occurrence of cancers with long latency periods.

> This study only suggests the possibility that the risk of death from soft tissue sarcomas, Hodgkin's disease, and testicular cancer are elevated among veterans who served in Vietnam.

6. "The preliminary results of the CDC Vietnam Experience Study released in 1987 showed excessive instances of lymphosarcomas, leukemia, and brain cancer among Vietnam veterans."

We are not aware of any report which fits this description. In any event, such findings were not reported by the Centers for Disease Control in their report on the physical health of Vietnam veterans published in the May 13, 1988, edition of the Journal of the American Medical Association. The authors summarized this portion of their study:

> In conclusion, most Vietnam veterans who participated in this study felt they were in good current health 15 to 20 years after service. However, Vietnam veterans more frequently reported current somatic symptoms and physician-diagnosed diseases than did non-Vietnam veterans. Most of these conditions were not currently detectable by the comprehensive physical and laboratory screening examinations used in this study. One physical difference that is still detectable is that Vietnam veterans, particularly those who served in tactical military occupational specialties, have greater hearing loss. Further, among the subsample of participants who had semen samples evaluated, there were certain differences in semen characteristics between Vietnam and non-Vietnam veterans. These included a decrease in the Vietnam veterans' sperm concentrations and a significant decrease in the average proportion of "normal" sperm cells. Despite these differences, Vietnam and non-Vietnam veterans have fathered similar numbers of children.

The authors also commented:

> The purpose of the (Vietnam Experience Study) was to evaluate health effects that may have resulted from the "general experience" of having served in Vietnam. In designing the telephone interview and the physical examinations, we used a broad approach but emphasized health conditions that have been suggested as being related to prior exposure to herbicides or dioxin. On examination, we found no differences

> between cohorts in these health effects, such as skin conditions, peripheral neuropathy, hepatic dysfunction, porphyria, lipid abnormalities, and impaired immune function.

Concerning reproductive outcomes, the authors stated:

> In summary, Vietnam veterans reported more adverse reproductive and child health outcomes in the telephone interview than did non-Vietnam veterans. However, results of a substudy of birth defects documented on hospital birth records showed that Vietnam veterans were not at increased risk of fathering children with birth defects evident at birth. These results are consistent with the findings of three epidemiologic studies conducted since 1981 on ~~the~~ relationship of Vietnam service and birth defects in children of male veterans.

7. "The VA Mortality Study released in 1987, a survey of 50,000 veterans, showed rates of death due to non-Hodgkin's lymphoma 110 percent higher than normal, and deaths due to lung cancer 58 percent higher than normal among Marines who served in areas heavily sprayed with Agent Orange."

The authors of that study noted that for most major causes of death, "the distribution of deaths for veterans who served in Vietnam is not markedly different from those who did not serve in Vietnam except for selected malignancies and 'accidents, accidental poisonings, and violence.'" Concerning malignancies, the authors stated, "When all malignancies were grouped together, Vietnam veterans did not exhibit an excess of cancer when compared to their counterparts who did not serve in Vietnam. Differences between the services, however, were seen for specific cancer sites among those who served in Vietnam relative to men who did not... The most interesting differences were the statistically significant elevation for lung cancer ... and non-Hodgkin's lymphoma ... seen in the Marines who served in Vietnam relative to Marines who served elsewhere. The risk for soft-tissue sarcoma was not elevated among Vietnam veterans as a whole or in any subgroup of these veterans."

The VA determined proportionate mortality ratios, which deal with proportion of all deaths due to a specific cause. These ratios do not indicate the rate of all deaths or of death from any one cause.

The VA sought the guidance and recommendation of the Congressionally established Veterans' Advisory Committee on Environmental Hazards concerning the results of this study. The Committee agreed that the findings of non-Hodgkins lymphoma and lung cancer were statistically significant. They further commented, however, that these results should be interpreted with caution and should not be considered to be conclusive.

8.

There are several reasons for this cautionary approach which was outlined for Senator Kerry in our letter of April 14, 1988.

> First, the mortality study was undertaken using a proportionate mortality analysis. This provided us with an opportunity to conduct a major mortality study in spite of the fact that data were not available on the size of the population among which the deaths occur. While it may not be the preferred technique for a study seeking definitive answers, it does provide a vehicle for obtaining tentative impressions. It is generally recognized to be a hypothesis-generating technique rather than a hypothesis-testing one.
>
> Second, a proportionate mortality study cannot by its very nature determine the question whether the observed results constitute a direct cause and effect relationship. One reason for this is that in a proportionate mortality study, one is looking at proportions of deaths within a given population rather than looking at rates of death. The study must begin and end with a total of 100% of the deaths being accounted for. Should there be a deficit, that is a less than expected proportion of deaths due to a given cause, then there must be a balancing excess of deaths due to another cause or causes. That excess may be real or it may be artificial. Only further analysis and study can resolve that issue.
>
> Third, the VA's proportionate mortality study cannot tell us what circumstance or event may have been responsible for the observed results. Nothing is known about the exposure opportunities the study's subjects may have had to Agent Orange or to any other substance. In the case of the lung cancer finding, it is well accepted that smoking plays the major role in its development. An effort was made to try to determine the smoking history of the Marines in the mortality study. Unfortunately, existing military records did not prove to be sufficiently detailed to enable the investigators to determine their smoking status.

8. "The 1987 Ranch Hand follow-up study showed excessive incidence of skin cancers, systemic neoplasms, lymphomas, soft-tissue sarcomas, three times as many cancers of the oral cavity and pharynx, twice as many cancers of the bronchus and lung, and three times the number of testicular neoplasms."

9.

The authors of that report arrived at a different conclusion about their findings:

> The results of the first follow-up study in 1985 have shown subtle but consistent narrowing of medical differences between the Ranch Hands and Comparisons since the Baseline Study in 1982. The 1985 examination results provide reassuring evidence that the current state of health of the Ranch Hand participants is unrelated to herbicide exposure in Vietnam. Continued close medical surveillance of these military populations is strongly indicated. This follow-up report concludes that there is not sufficient plausible or consistent scientific evidence at this time to implicate a causal relationship between herbicide exposure and adverse health in the Ranch Hand group.

The authors also stated:

> The overall pattern of these findings indicates that this followup study cannot be viewed as alarming from the traditional perspectives of clinical medicine or epidemiology. This study, in fact, demonstrates similarity in current health status between the Ranch Hand and Comparison groups.

Regarding malignancies, the authors reported:

> Skin and systemic cancers, both suspected and verified by medical records, showed no significant group differences for the Baseline-followup interval (1982-1985). However, for all neoplasms combined (malignant, benign, and uncertain), a borderline significant excess in the Ranch Hand group was noted in an unadjusted analysis. The analyses of interval cancers revealed group interactions for verified and verified plus suspected basal cell carcinoma and verified plus suspected systemic cancers. Nonsignificant findings were observed for verified and verified plus suspected sun exposure-related cancers. Verified systemic cancers did not differ significantly between groups.

> The analyses of lifetime cancer found significant results for verified basal cell carcinoma and verified sun exposure-related skin cancers. Group interactions were noted for systemic cancer categories and for verified plus suspected basal cell carcinoma. The higher rate of basal cell carcinoma in the Ranch Hands versus the Comparisons found at Baseline was nonsignificant for the followup interval, but due to the effect of the larger number of Baseline cases and the significant confounding of average residential latitude, the adjusted analysis of lifetime basal cell carcinoma emerged as statistically significant.
>
> There were several disparities in the distribution of testicular, colon, and smoking-related tumors in the groups. Further, one case of soft tissue sarcoma and one possible lymphoma (both in Ranch Hands) were diagnosed in the interval, balancing the two similar cases found in the Comparison group at Baseline. Considering that the systemic cancer curves are in their early stages for both groups, with perhaps insufficient latency, the cancer results of the followup examination should not be viewed as disturbing, but as cause for continued monitoring. (Emphasis added.)

9. "And the report released on the Ranch Hand study in March 1988 ... showed higher incidences of tumors, birth defects, psychological disorders, blood toxicity, and cardiovascular problems."

This report reviewed the findings of the first morbidity report of the Ranch Hand study which had been published in 1984. The Dioxin Panel of the Veterans' Advisory Committee on Environmental Hazards reviewed this March paper in May 1988. Their principal criticism was that the author had failed to take into account the morbidity data which had become available subsequent to the 1984 report. The panel thought this significant because trends that were observed in the 1984 data did not continue in the 1988 data. Furthermore, the panel noted, many of the inferences derived from the 1984 data were incorrect when reviewed in the light of the 1988 data.

APR 14 1988

Honorable John Kerry
United States Senate
Washington, D.C. 20510

Dear Senator Kerry:

I am writing in response to your statement in the Congressional Record of March 2, 1988, entitled, "Justice for Victims of Agent Orange." You express dissatisfaction with the fact that "Vietnam veterans are still not receiving any compensation from the Federal Government for diseases caused by agent orange." You go on to cite an article by Paul Eagan entitled, "Does Congress Hide Behind Science on AO Issue?" and describe it as a clear and cogent analysis of the Agent Orange issue. Several comments made in that article need to be addressed and the record needs to be set straight if one is to discuss the difficult and emotional issue of Agent Orange fairly.

Regarding the Veterans Administration's "Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War," the article correctly reports that there was a statistically significant increased proportionate mortality ratio for non-Hodgkins' lymphoma and lung cancer among Marines serving in I Corps. However, the article then states that the "VA immediately characterized the study's findings as a statistical fluke - as having little merit in ascertaining a scientific relationship between exposure to dioxin and specific diseases." This statement bears little resemblance to the actual position of the Veterans Administration. We have not dismissed this study as is suggested by the author. Rather, we have stated that the study is of concern to us and identified issues requiring further study and analysis. There are several reasons for this.

First, the mortality study was undertaken using a proportionate mortality analysis. This provided us with an opportunity to conduct a major mortality study in spite of the fact that data were not available on the size of the population among which the deaths occurred. While it may not be the preferred technique for a study seeking definitive answers, it does provide a vehicle for obtaining tentative impressions. It is generally recognized to be a hypothesis-generating technique rather than a hypothesis-testing one.

Second, a proportionate mortality study cannot by its very nature determine whether the observed results constitute a direct cause and effect relationship. One reason for this is that in a proportionate mortality study, one is looking at proportions of deaths within a given population rather than looking at rates of death. The study must begin and end with a total of 100% of the deaths being accounted for. Should there be a deficit, that is a less than expected proportion of deaths due to a given cause, then there must be a balancing excess of deaths due to another cause or causes. That excess may be real or it may be artificial. Only further analysis and study can resolve that issue.

Third, the VA's proportionate mortality study cannot tell us what circumstance or event may have been responsible for the observed results. Nothing is known about the exposure opportunities the study's subjects may have had to Agent Orange or to any other substance. In the case of the lung cancer finding, it is well accepted that smoking plays the major role in its development. An effort was made to try to determine the smoking history of the Marines in the mortality study. Unfortunately, existing military records did not prove to be sufficiently detailed to enable the investigators to determine their smoking status.

Rather than simply pronounce the issue unanswerable, the VA has committed itself to going forward. First, the VA is updating the mortality study to include an additional 11,000 deaths of Vietnam era veterans. This will give added strength to the study's findings and cases with longer latency periods will be added to the study. This is important because there may be a long latency period between service in Vietnam and the subsequent manifestation of non-Hodgkin's lymphoma. It is important to continue the data collection in order to preclude premature and potentially misleading or incorrect conclusions.

Second, a separate analysis is planned for Army Vietnam veterans who served in I Corps, the area of Vietnam where Marine Corps veterans predominantly served. This is an effort to determine whether Army veterans who served in the same geographic region of Vietnam as Marines experienced similar mortality patterns.

Third, a separate mortality study is planned exclusively for Marine Vietnam veterans. It is hoped that this effort will produce overall mortality rates and cause-specific mortality rates for Marine Vietnam veterans.

Finally, the VA is reviewing the Patient Treatment File, a computerized data base containing summary information about veterans who have received hospital care from the VA. Attention will be focused on non-Hodgkin's lymphoma and Hodgkin's disease. The cases and controls will be compared with respect to service in Vietnam and other military service factors. If military service in Vietnam is not associated with an increased risk of non-Hodgkin's lymphoma or Hodgkin's disease, then the proportion of veterans who served in Vietnam or who have certain military characteristics should be similar for both the controls and the cases.

This last point is important because the article states "virtually hundreds of thousands of veterans have been treated, but the VA has never attempted to evaluate the resulting data. Why the VA has never undertaken such an analysis is an open question." This assertion is wrong. The VA has, in fact, examined the data in the Patient Treatment File. A study by Kang et al., "Soft-Tissue Sarcomas and Military Service in Vietnam: A Case Comparison Group Analysis of Hospital Patients" was published in the Journal of Occupational Medicine (vol. 28, pp. 1215-1218 (1986)). That case-comparison study looked at the VA's Patient Treatment File to identify all Vietnam era veterans whose conditions were diagnosed as soft-tissue sarcomas from 1969 to 1983. There were 234 cases identified. A comparison group consisted of 13,496 patients systematically sampled from the same Vietnam era patient population from which the cases were drawn. Military service information was obtained and analyzed. The authors found no significant association of soft-tissue sarcomas and military service in Vietnam.

In addition to this study, the VA has been monitoring the data collected from the Agent Orange Registry program. To date there have been no unusual patterns of disease detected either as to rate or the age of occurrence among the over 200,000 participants in the Registry.

Caution must be exercised in interpreting the information in the Registry, however. The information obtained from the veterans who participated in the Registry program was for the purpose of determining their health status and not as part of a carefully designed scientific study. Also, the veterans who participated in the Agent Orange Registry are a self-selected group, many of whom had no physical complaints. Most scientists would agree that reliance upon a self-selected study population should be avoided.

The VA is accused of having a "foot-dragging attitude in awarding compensation for disabilities associated with Agent Orange." The inference of that accusation is that there are disabilities which the scientific community agrees are associated with exposure to Agent Orange. The position taken by the Veterans Administration is similar to that of the American Medical Association expressed in 1988 when it concluded:

> The studies to date on the human health effects of Vietnam exposures to Agent Orange do not reveal a clear relationship between serious illness and exposure. A number of important studies are still in progress; until they or others that may be deemed necessary are completed, no final conclusions can be drawn. . . . A wide range of adverse reactions in animals has been observed, which are species-dependent. . . . Except for chloracne, however, TCDD has not demonstrated comparable levels of biologic activity in man; that is to say, no long-term effects on the cardiovascular and central nervous systems; the liver, the kidney, the thymus and immunlogic (sic.) defenses, and the reproductive function -- in the male, female, or offspring -- have been demonstrated.

A similar conclusion was expressed by Judge Weinstein when he issued an opinion approving the settlement of the Agent Orange litigation and by the Second Circuit when it affirmed his decision. It can hardly be said, therefore, that the VA is "foot-dragging" when its opinion and conclusions are similar to those expressed by disinterested bodies.

The article also makes improper inferences when it suggests that Vietnam veterans could have had higher levels of dioxin in their bodies than the general population if current levels were extrapolated back in time to their periods of service in Vietnam.

The argument presented is that looking at the half life of dioxin, which is estimated to be 7 years, the Vietnam veterans would be expected to have three times the background levels found among the general population today. The experience with the Ranch Hand study results, however, points out the fallacy of this argument. When the assay is performed on individuals who were known to have had high exposure to Agent Orange during their tour of duty in Vietnam, their dioxin levels are considerably higher today than the general background levels. This suggests that even with the half life of 7 years, if Vietnam veterans as a whole had experienced significant exposure to Agent Orange, it would still be reflected by higher dioxin levels today. The CDC effort demonstrates that this is not the case. Additionally, if we were to assume that Mr. Fagan's argument is correct, that Vietnam veterans did have higher levels of dioxin in their bodies 15 years ago, there is still no known association between levels of dioxin in body tissue and adverse health. In fact, the Ranch Hand experience would suggest that there is no relationship between either past or present high levels of dioxin and current impaired health.

Finally, the article casts aspersions upon the work of the Veterans' Advisory Committee on Environmental Hazards. The article states that "(t)hat committee was to have surveyed the existing and ongoing scientific dioxin studies. It was then to have recommended diseases reasonably associated with dioxin for compensation purposes." That is an accurate description of the Committee's mandate and to date, it has specifically reviewed over 60 papers or articles dealing with this subject. Even more important, members of the Dioxin Panel of the Scientific Council are experts who have worked extensively in the area of the health effects of exposure to a variety of substances, including dioxin, and are equipped to bring to bear their expertise to issues brought before the Committee.

The article incorrectly states, "True to its long-standing reputation for failing to meet its responsibilities on the Agent Orange issue, however, the VA manipulated the committee's scope of dioxin literature review in order to prevent awarding compensation." The VA has never limited the scope of the Committee's review and has repeatedly stated its willingness to bring studies to the Committee's attention from a variety of sources including members of Congress, interested citizens, state Agent Orange programs, and veterans and their organizations. One such organization has been noticeably absent in this process. The Vietnam Veterans of America, despite several direct invitations to do so, has never identified a single study it desired to have reviewed by the Committee. Rather it has insisted that the Committee must review paper by paper the literature on Agent Orange, its constituents, and its contaminant dioxin, in its entirety before the Vietnam Veterans of America would accept their judgment. Given the thousands of papers in the scientific literature, this is an unrealistic request. The VA has attempted to focus the Committee's attention on human studies and on the studies most often cited as demonstrating a causal association. I renew again my invitation to veterans organizations and to the public to bring to my attention specific studies that they believe the Committee should review and I shall ask for such a review.

I believe that the Veterans Administration has responded to the difficult and complex question of the effects of exposure to Agent Orange in a responsible and responsive way. We have been steadfast in our commitment to pursue the scientific truth wherever it may take us. We recognize that our solemn obligation to the veterans of this country would permit us to do no less. Let us work together as we fulfill that obligation.

Sincerely,

THOMAS K. TURNAGE
Administrator

TESTIMONY BEFORE THE SENATE VETERANS COMMITTEE

MAY 12, 1988 - 8.00 A.M.

THE HONORABLE DON NEWMAN
CHAIRMAN
DOMESTIC POLICY COUNCIL, AGENT ORANGE WORKING GROUP

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, GOOD MORNING! I AM DON NEWMAN, CHAIRMAN OF THE DOMESTIC POLICY COUNCIL AGENT ORANGE WORKING GROUP.

AS YOU KNOW, SINCE 1979 THE WORKING GROUP HAS SERVED A COORDINATING ROLE WITHIN THE GOVERNMENT. IN ADDITION TO FACILITATING DISCUSSIONS AMONG FEDERAL AGENCIES AND DEPARTMENTS REGARDING AGENT ORANGE RESEARCH DIRECTION, IT HAS ASSURED SCIENTIFIC PEER REVIEW OF PROTOCOLS AND SUBSEQUENT STUDIES.

I AM HAPPY TO REPRESENT AN ADMINISTRATION THAT HAS FOCUSED THE HIGHEST LEVELS OF GOVERNMENT RESEARCH ON THE HEALTH OF VIETNAM VETERANS.

I BRING GOOD NEWS. AFTER ALMOST TEN YEARS OF EFFORT AND THE EXPENDITURE OF $90 MILLION DOLLARS ON SCIENTIFIC RESEARCH OF VETERANS BY SEVERAL AGENCIES, WE CAN SEE THE LIGHT AT THE END OF THE TUNNEL.

TODAY, WE SHARE WITH YOU CONCLUSIONS BASED ON GOOD SCIENCE WHICH WILL GIVE US, THE CONGRESS, AND VIETNAM VETERANS, CAUSE TO BE REASSURED THAT THEIR SERVICE IN VIETNAM AND POSSIBLE EXPOSURE TO AGENT ORANGE ARE NOT RESULTING IN ADVERSE HEALTH AFFECTS.

THE VETERANS ADMINISTRATION, DEPARTMENT OF DEFENSE (UNITED STATES AIR FORCE) AND CENTERS FOR DISEASE CONTROL WILL PROVIDE YOU DETAILS OF THE STATUS AND FINDINGS OF THE KEY STUDIES OVER WHICH THE AOWG HAS HAD OVERSIGHT.

THEY ARE:

THE DOD RANCH HAND STUDY (USAF)
THE CDC VIETNAM EXPERIENCE STUDY
THE CDC STUDY OF SELECTED CANCERS
THE CDC AGENT ORANGE STUDY
THE VA MORTALITY STUDY AND OTHER RELATED STUDIES

THE KEY POINT I WISH TO MAKE TODAY IS THAT IN THE STUDIES WHICH HAVE COME TO CONCLUSION, WE ARE SEEING NO CAUSE-EFFECT RELATIONSHIP BETWEEN SERVICE IN VIETNAM AND POSSIBLE EXPOSURE TO AGENT ORANGE AND ADVERSE HEALTH. THE STUDIES CONCERNING THE GROUND TROOPS SHOW LITTLE OR NO INCREASE IN DIOXIN LEVELS IN THESE TROOPS. AS YOU WILL HEAR IN OTHER TESTIMONY, IT DOES NOT NOW APPEAR THAT THE AVERAGE VIETNAM VETERAN IS AT RISK FROM AGENT ORANGE EXPOSURE. SCIENTIFIC EVIDENCE DOES NOT SUPPORT THE CLAIM OF MAJOR INCREASES IN ILL HEALTH CAUSED BY EXPOSURE TO AGENT ORANGE.

I, THEREFORE, AGREE WITH THE POSITION TAKEN BY THE VA, IN OPPOSING THE ENACTMENT OF S.1692 AND S.1787. IT IS NOT SOUND PUBLIC POLICY TO MAKE A SWEEPING PRESUMPTION SUCH AS THOSE IN S.1692 AND S.1787 WHICH APPEAR TO BE BASED ON FRUSTRATION OR THE LACK OF SCIENTIFIC EVIDENCE TO SUPPORT DESIRED CONCLUSIONS.

I REGRET, THAT I HAVE ANOTHER MEETING TO ATTEND, BUT, DR. MASON WHO AT ONE TIME ACTED AS CHAIR OF THE AOWG HAS MY FULL CONFIDENCE AND CAN ANSWER THE SCIENTIFIC QUESTIONS FOR ME AND WITH HIM IS DR. HOUK, THE FORMER CHAIR OF THE AOWG SCIENCE PANEL. ADDITIONALLY, DR. PETER BEACH, THE EXECUTIVE SECRETARY OF THE AOWG, CAN ANSWER ANY QUESTIONS OF AN HISTORICAL NATURE.

THANK YOU MR. CHAIRMAN.

Study of Vets Raises Questions

Health Exams Contradict Some Assertions

5-12-88

By Michael Specter
Washington Post Staff Writer

Vietnam veterans are far more likely to suffer from depression, anxiety and alcoholism than veterans who served elsewhere, according to a comprehensive federal study released yesterday.

The study, commissioned by Congress and carried out by the Centers for Disease Control (CDC), was the first major attempt to assess the health of Vietnam veterans by comparing them to men of the same age who served elsewhere at the same time.

More than 15,000 men who entered the U.S. Army between 1965 and 1971 participated in telephone interviews for the project. Of those, 4,462 were selected randomly to receive extensive physical and psychological evaluations.

Vietnam veterans also were much more likely to suffer from hearing loss and low sperm counts, the study found. But, despite the fact that the Vietnam veterans reported almost twice as many physical illness as those who did not serve in Vietnam, researchers found that, in most respects, the physical health of both groups was identical.

"We are not trying to minimize the psychological or physical problems of Vietnam veterans," said Dr. Scott F. Wetterhall, a CDC epidemiologist who worked on the project. "But at the same time, given the common stereotypes of Vietnam vets as mentally disturbed and socially maladjusted, it seems important to point out that in the vast majority of cases the facts do not support that view."

Most medical experts concede that the potential health problems of Vietnam veterans were ignored for years after the war. It has been more than 20 years since the first soldiers returned from battle, and almost since that time scientists have debated how to evaluate their health.

Results of the "Vietnam Experience Study" will be published in Friday's issue of the Journal of the American Medical Association. Although the Journal provided advance copies on the understanding that the results were not to be released until Friday, the news embargo was broken.

The study addresses three aspects of the veterans: psychological characteristics, physical health and the health of their children.

Many soldiers in Vietnam were exposed to Agent Orange, a herbicide that contains dioxin, which is a suspected carcinogen.

The numbers of Vietnam veterans who reported that they had skin diseases and that their children were born with birth defects was far greater than for those who did not serve in Vietnam.

Although the Vietnam group reported that their children had birth defects at a rate of 65 per thousand, compared with 50 per thousand for the veterans who served elsewhere, hospital records showed a much lower rate of 29 per thousand compared to 24 per thousand, according to the CDC researchers.

"These birth defects and low sperm counts and skin conditions are very disturbing to us," said Mary Stout, president of the Vietnam Veterans of America. "Those numbers are frightening. If the Vietnam veterans report greater numbers of illness, it's because they have experienced so much more of it, and they are more aware of being sick than the others."

CDC officials said they were not certain how to explain the large difference between health problems reported by Vietnam veterans and problems actually found upon examination.

Fifteen percent of the Vietnam group had experienced combat-related post-traumatic stress disorder since returning home. Almost half reported being jumpy or easily startled, and a third said they had trouble sleeping.

The CDC is continuing a large study of cancers suspected of being associated with Agent Orange, and results will be completed later this year. Earlier studies have shown no significant relationship between exposure to the defoliant and increased incidence of cancer.

Although researchers found lower sperm counts among the Vietnam group, they could not account for it. Whether or not a veteran served in Vietnam, poor psychological status was more prevalent among those who were not white, who had been younger than 19 when they enlisted, or who had low scores on Army technical tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

Testimony of

James O. Mason, M.D., Dr.P.H.
Director, Centers for Disease Control
U.S. Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

before the

U.S. Senate
Committee on Veterans Affairs

Thursday, May 12, 1988

8:00 a.m.

Room 418, Russell Senate Office Building

INTRODUCTION

Good morning, Mr. Chairman, I am Dr. James O. Mason, Director, Centers for Disease Control (CDC). I welcome this opportunity to appear before this committee to describe the progress of the studies of the health of Vietnam veterans being conducted by the Centers for Disease Control.

With me this morning is Dr. Vernon Houk, Director of CDC's Center for Environmental Health and Injury Control, who has had oversight responsibility for these studies since their initiation.

BACKGROUND

Public Laws 96-151 and 97-72 directed the Veterans Administration (VA) to conduct investigations of Vietnam veterans' health. The first of these laws, signed in December 1979, required a study to assess the possible health effects of exposure to herbicides, primarily Agent Orange, during the Vietnam conflict. The second, signed in November 1981, expanded the scope of the study to allow for the inclusion of other environmental hazards associated with service in Vietnam. CDC was assigned the responsibility for design and conduct of the studies in January 1983 by an Interagency Agreement with the Veterans Administration (VA). CDC also conducted a Birth Defects Study among Vietnam veterans, which was a separate research effort supported by Department of Defense (DOD), the VA, and CDC. The results of that study were published in 1984 and have been previously reported to you.

In May of 1983, CDC completed and submitted a draft research protocol for scientific review and comment by four groups: the Office of Technology Assessment (OTA), the Science Panel of the Cabinet Domestic Policy Council Agent Orange Working Group (AOWG), the HHS Advisory Committee on Special Studies Relating to the Possible Long Term Effects of Phenoxy Herbicides and Contaminants (the Ranch Hand Panel), and CDC's own Ad Hoc Review Panel. The CDC received comments from these groups by September 1983.

The final protocol for these studies was published in November 1983. It incorporated modifications suggested by the scientific reviews and stated that the studies were designed to allow for the addition of procedures or questions based on interim analyses of the data or data from sources outside these studies. Three independent but related studies comprise CDC's Agent Orange Projects:

1. The Vietnam Experience Study: a study of the long-term health effects of military service in Vietnam.
2. The Agent Orange Study: a study of the long-term health effects of exposure to herbicides in Vietnam.
3. The Selected Cancers Study: a study to determine the risks of specific cancers among Vietnam veterans.

I will summarize the status of these three studies, beginning first with the Selected Cancers Study.

STATUS OF THE SELECTED CANCERS STUDY

The Selected Cancers Study was designed to evaluate if Vietnam veterans are at increased risk of developing certain cancers which have been identified in the scientific literature as possibly associated with industrial or occupational exposure to phenoxy herbicides or chlorophenols and their dioxin contaminant. These cancers are: lymphoma (including Hodgkin's disease and non-Hodgkin's lymphomas), soft tissue sarcoma, nasal and nasopharyngeal cancer, and primary liver cancer.

This case-control study was designed because the sample sizes of the proposed cohort studies (the Vietnam Experience and Agent Orange Studies) were not large enough to provide answers about these relatively rare cancers. Case ascertainment by the eight participating cancer registries began in December 1984 and will continue through November 1988. The controls are selected from the same eight geographic areas through a random digit dialing process. As cases and controls are identified, it is not known whether they are military veterans and, if they are veterans, whether they served in Vietnam. That information is obtained during the interview process along with other data on risk factors for these cancers.

As of March 31, 1988, interviews have been completed on approximately 2100 cases and 1700 controls. The interviews and validation of diagnosis by pathology tissue review will be completed in the summer of 1989. Data analysis should be completed in late 1989 and the results published in 1990.

Next, I will address the Agent Orange Study.

STATUS OF THE AGENT ORANGE STUDY

The Agent Orange Study was designed to evaluate the possible health effects of exposure to Agent Orange in Vietnam veterans. The implementation of the Agent Orange study was dependent on the development of a scientifically valid herbicide exposure index based on information contained in military records. As cautioned in the 1983 protocol, since many of the proposed categorization procedures were untested, pilot study assessments were necessary before a final decision could be made to proceed with a full-scale study.

As a result of intensive work between 1983 and 1986 by the U.S. Army and Joint Services Environmental Support Group and CDC, a Science Subpanel of the Agent Orange Working Group concluded in June 1986 that a "scientifically valid study based on military records was not possible without an independent method of exposure verification." During early 1986 CDC had already begun work to develop a new laboratory method utilizing blood to establish current body burdens of dioxin as an indicator of previous exposure to dioxin-containing substances such as Agent Orange. The CDC scientists were successful and this new method, utilizing blood serum, is a more feasible approach for testing groups of individuals than previous methods, which measured dioxin in adipose (fat) tissue. A protocol for a "Validation Study Comparing Military Records-based Estimates of the Likelihood of Exposure to Agent Orange with Current Serum Levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)" was developed by CDC and approved by the AOWG Science Panel and OTA in October 1986.

The results of this Validation Study, released in July 1987, showed no association between serum TCDD levels and several different military records-based estimates of the likelihood of Agent Orange exposure. Also, there was no association between TCDD levels and self-reported exposure obtained directly from the veteran. Among the 646 Vietnam veterans for whom TCDD levels were obtained, the median TCDD level was 3.8 parts per trillion (ppt), with a range from less than 1 to 45 ppt. The median TCDD level for the 97 non-Vietnam veterans was also 3.8 ppt, with a range from less than 1 to 15 ppt. Nine Vietnam veterans (about 1% of the sample) and 3 non-Vietnam veterans (about 3% of the sample) had current TCDD levels greater than 10 ppt (ATTACHMENT A). Two Vietnam veterans had levels above 20 ppt, one with 25 and another with 45 ppt; no non-Vietnam veterans had levels above 20 ppt. The veteran with a level of 45 ppt reported no exposure (military or civilian) to herbicides; the veteran with a level of 25 ppt reported 180 days of indirect military exposure (defined as walking through, or clearing vegetation in, a previously sprayed area), plus one day of home use, but no other exposure. During the telephone interview, both of these men reported their health as "excellent," with no health problems perceived as a consequence of exposure to Agent Orange.

The methods CDC used for selecting individuals and classifying herbicide exposure in this TCDD Validation Study have been criticized, particularly by persons associated with the New Jersey Pointman project. The focus of the criticism is the so-called "hits" model used for selecting men into the study. This model computes for each veteran a "hits score"--the sum of all the occasions for which a veteran's company was within 2 kilometers of an area sprayed by Agent Orange in the previous 6 days. (A higher score in this model means a greater opportunity for exposure.) If we had only evaluated the "hits" model, the critics would be correct. However, we also compared serum TCDD levels with several other exposure models, including two which are similar to those being used by the New Jersey group. One such model is the number of days a man spent in any of the five most intensely sprayed areas, and the other is the amount of direct or indirect exposure reported by the veteran himself. For example, 25% of our study group said they had been directly exposed. These men, including those reporting current health problems, showed TCDD levels no higher than the others. A final point to consider in evaluating the potential for exposure in this group of 646 Vietnam veterans is that they served an average of 320 days in tactical battalions which operated in the heaviest sprayed area of Vietnam (III Corps) during the peak years of Agent Orange spraying (1966-1969).

At the same time the Validation Study was being carried out, CDC was measuring TCDD levels on a group of Air Force Health Study participants (which consists of Ranch Handers and a comparison group) in the U.S. Air Force and CDC study of the half-life (the time it takes the body to eliminate half of a substance) of TCDD. Of the 147 Ranch Handers whose TCDD values were measured, 25 had current TCDD levels of between 50-100 ppt, 16 between 100-200 ppt, and 5 over 200 ppt; all but one of the 49 veterans in the comparison group had TCDD values less than 10 ppt (ATTACHMENTS B and C). The Air Force/CDC Half-Life Study, a National Institute for Occupational Safety and Health (NIOSH) Pilot Study of herbicide production workers, and the New Jersey Pointman Project have all detected substantially elevated TCDD levels in occupationally exposed individuals whose last known exposure occurred 15 to 20 or more years ago.

The published results from New Jersey's project are also consistent with findings from CDC's TCDD Validation Study in that participants in the New Jersey study who did not handle Agent Orange directly as an occupational duty did not have elevated TCDD levels upon examination in 1987. The measurement of adverse health effects in those who were exposed sufficiently to have TCDD levels still elevated at present is being carried out in the Air Force Health Study and NIOSH studies, where such individuals are being carefully and, in the case of Air Force Health Study, repeatedly examined, including individual serum TCDD levels being measured by CDC.

As a result of their reviews, both AOWG and OTA concluded in September 1987 that it is not possible to design a large scale epidemiologic study to look for effects of Agent Orange in ground troops who served in Vietnam. Accordingly, AOWG instructed CDC to begin the process of canceling the data collection contracts and closing out all activities related to the Agent Orange Study. CDC is currently negotiating the settlement costs with the contractors related to the termination of this study.

Last, I will summarize the status of the Vietnam Experience Study.

STATUS OF THE VIETNAM EXPERIENCE STUDY (VES)

The Vietnam Experience Study was designed to evaluate possible health effects of the "general Vietnam experience" by comparing the health status of a cohort of male U.S. Army veterans who served in Vietnam with a cohort of male U.S. Army Vietnam-era veterans who served elsewhere. This study was initially designed with three main components: a mortality assessment, telephone interviews, and medical and psychological examinations. Based on interim analyses of the data and the experience of the Ranch Hand Study (related to acquisition of birth records), CDC added to the Vietnam Experience Study a birth outcome validation component and a semen analysis component.

I will describe the general findings of the Vietnam Experience Study, starting with the Mortality Assessment component, which was published in February 1987. Then, I will address the morbidity findings which are being published in this week's Journal of the American Medical Association. It is important to note that we had originally planned to publish the morbidity findings sequentially as the various components were completed. However, we subsequently decided, with input from Congressional staff and OTA, to publish the results simultaneously. This decision was made because of concerns related to releasing self-reported interview data separately from the medical examination and birth outcome validation data.

Mortality Assessment Component of the VES

The Vietnam Experience Study used a random sample of military records to find 9,324 male U.S. Army veterans who served in Vietnam and 8,989 Army veterans who served in Korea, Germany, or the United States during the same time period. All of these men had been discharged alive with a rank of E1-E5 after a single enlistment starting between 1965 and 1971.

Over the entire follow-up period (from discharge through December 1983), total mortality among the Vietnam veterans was 17% higher than for the other veterans. The excess mortality occurred mainly in the first 5 years after discharge from active duty, when the death rate among Vietnam veterans was about 45% higher than the rate of non-Vietnam veterans. Most of the increased mortality was from external causes, such as motor vehicle injuries, suicide, and homicide. After the first 5 years, mortality among Vietnam veterans was similar to that of non-Vietnam veterans, except for drug related deaths, which continued to be elevated.

The overall finding of excess postservice mortality due to external causes among Vietnam veterans was similar to that found among men returning from combat areas after World War II and the Korean War. An unexpected finding in this study was the lower rate in deaths from diseases of the circulatory system among Vietnam veterans compared to non-Vietnam veterans.

As mentioned above, the first mortality report includes deaths identified through 1983. We have recently updated this through 1986. With the exception of the first 5 years following discharge from military service, Vietnam veterans continue to have a similar rate of all-cause mortality (rate/1000=1.7) compared to non-Vietnam veterans (rate/1000=1.8). A complete cause of death analysis which included these additional years, 1984-1986, should be completed by August 1988.

Morbidity Findings of VES

Attached to my testimony is a summary table of the significant findings from this component of the Vietnam Experience Study (ATTACHMENT D). In presenting these findings, I would like to point out that there are no comparable morbidity data from previous wars, as there was for mortality data. Therefore, it is not possible to compare morbidity data from the Vietnam Experience Study with data on veterans of previous wars. I will discuss the findings of the telephone interview, the medical and psychological examination, and the reproductive and child health components of this study.

Telephone Interview:

In the telephone interview component, nearly 18,000 veterans (whose addresses on their military records date from the late 1960s) were traced with 94% of the Vietnam and 92% of the non-Vietnam men located during 1985-1986. Of the men located, 93% of the Vietnam and 91% of the non-Vietnam men were interviewed, a tribute to their extraordinary spirit of cooperation.

The interviews revealed a broad similarity between the two groups in terms of current demographic and social characteristics, such as education, income, employment rates, and marital status. Although the two groups are very similar socioeconomically, the Vietnam veterans reported more current limitations in activities, more current use of prescription drugs, and a greater prevalence of many types of diseases and somatic and psychological symptoms. Also, while this study was not large enough to evaluate risks of specific types of cancers, the two groups were similar in the total reported number of physician-diagnosed cancers. The Vietnam veterans reported more problems with impaired fertility, yet both groups reported fathering the same average number of children. The Vietnam veterans also reported more birth defects and other health problems among their children. The verification of these findings is addressed later in this testimony.

Medical and Psychological Examinations:

In the examination component, we invited a random subsample (approximately 42%) of interviewed men for comprehensive physical, psychological, and laboratory examinations. Physical and laboratory examinations showed few current differences between the two groups, despite the many differences elicited by telephone interview. For example, there were large differences in skin problems reported during the telephone interview, but on examination all skin conditions, including scars from possible past chloracne, were found with similar frequency. Skin examinations were carried out by board-certified dermatologists who were not told whether the man being examined was a Vietnam or a non-Vietnam veteran.

Psychological evaluation of the men who were examined was done through standardized interviews and questionnaires. Although most men in both groups fell within normal limits in these evaluations, current psychological problems [primarily alcohol abuse or dependence (13.7% versus 9.2%), anxiety (4.9% versus 3.2%), or depression (4.5% versus 2.3%)] were more prevalent among Vietnam than non-Vietnam veterans.

Analysis of combat-related post-traumatic stress disorder was limited to Vietnam veterans. About 15% of these veterans reported ever experiencing symptoms which met diagnostic criteria for this disorder. Combat-related psychological symptoms diminished over time, but 2% still experienced episodes of post-traumatic stress disorder during the month before examination, up to 20 years after their service in Vietnam.

Overall, hundreds of physical health items were evaluated as part of the examinations, including blood pressure, electrocardiograms, Doppler examinations of peripheral arteries, chest roentgenograms, and pulmonary function tests, visual acuity and hearing tests, peripheral nerve function, immunologic status, and over 100 laboratory assays. For most items, no statistically significant differences were found between the two groups. The most noteworthy differences were hearing loss, stool occult blood, evidence of past infection with hepatitis B, lower sperm concentrations, and lower average proportions of morphologically "normal" sperm cells. Despite these last two findings, the average number of children fathered per veteran in each cohort after assignment to primary tour of duty was identical--1.6 children.

Reproductive Outcome Findings of the VES

Although Vietnam veterans reported more adverse reproductive and child health outcomes than non-Vietnam veterans during the telephone interview, the children of Vietnam veterans were no more likely to have birth defects (all types combined) recorded on hospital birth records than were children of non-Vietnam veterans. These results are consistent with the findings of three epidemiologic studies (the Australian birth defect study, the CDC birth defects study, and the U.S. Air Force Ranch Hand Study) conducted since 1981 on the relationship of Vietnam service and birth defects in children of male veterans. In addition, the recently published study of birth defects in the Seveso, Italy, area, which was contaminated by TCDD in 1976, concluded "that the data collected contain no evidence to support the position that in the population of the Seveso area exposed to TCDD, there was greater risk of producing congenitally malformed offspring." However, the authors cautioned that "the number of exposed pregnancies was not big enough to detect a low and specific teratogenic risk increase."

National Institute for Occupational Safety and Health Production Workers Study.

The National Institute for Occupational Safety and Health is doing a cohort mortality study and maintains a registry of approximately 7,000 workers who were employed at 14 plants in the production of chemicals that were contaminated with 2,3,7,8-TCDD. This study should be completed in FY 1989.

In addition, NIOSH is doing a cross-sectional morbidity study of workers from 2 of these 14 plants. This study will include data from interviews of approximately 350 production workers with occupational risk of high exposure and from physical examinations of about 275 of the workers interviewed. Blood concentrations of TCDD will be measured to determine the probable extent of exposure to TCDD. TCDD levels are also being measured on a comparison group of unexposed individuals matched on age, sex, race, and neighborhood. Based on hyphotheses already in the published literature of animal and human studies related to dioxin exposure, the NIOSH study has been designed to identify effects of exposure to TCDD on reproductive, hepatic, neurologic, immunologic, and psychologic disorders. This study is to be completed in FY 1990.

Specific Conditions Related to Pending Legislation

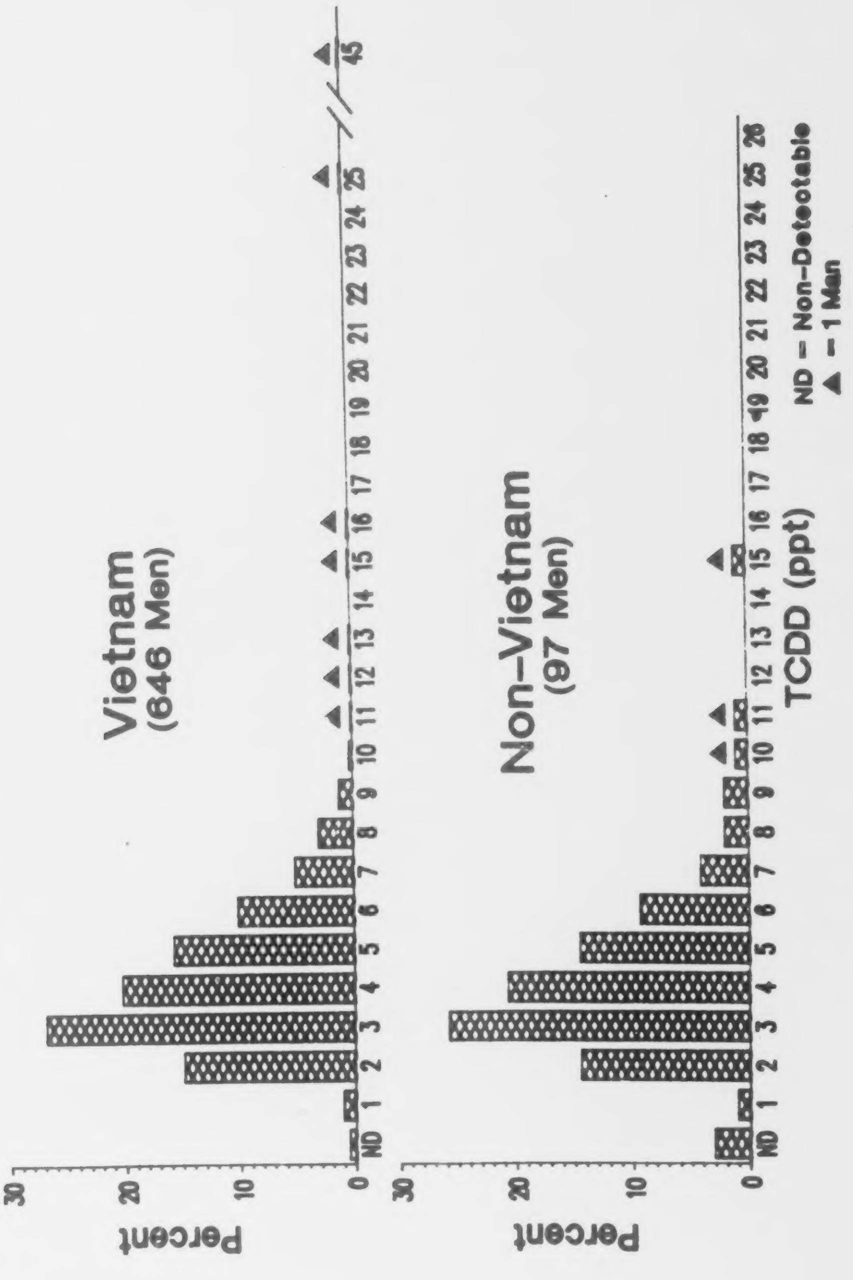
I am aware of pending legislation, S. 1692 and S. 1787, proposing that lung cancer, non-Hodgkin's lymphoma, and certain undefined immunodeficiency syndromes be considered as compensable in Vietnam veterans. In presenting the data in these areas from the Vietnam Experience Study, I want to caution that the number of specific types of cancer are too few for drawing conclusions.

As for lung cancer, one unconfirmed case has been reported in the Vietnam group and three cases, two of which have been confirmed, in the non-Vietnam group. Also, six cases of non-Hodgkin's lymphoma, three confirmed, have been reported in the Vietnam group and one case, confirmed, in the non-Vietnam group. As mentioned earlier, these numbers are too few for drawing conclusions.

Additionally, we tested all of the examined men for cell-mediated immuno-deficiency and laboratory assays of T & B lymphocytes, and found no evidence of any differences between the Vietnam and non-Vietnam groups in these immune system measurements.

In addition to the articles in the Journal of the American Medical Association, CDC is publishing a multi-volume monograph on the Vietnam Experience Study. These documents, containing thousands of pages, provide a comprehensive, detailed summary of the data collection procedures, study methods, and results for this study. These documents are currently being edited and we will provide these as soon as they are printed, hopefully in August. However, I am submitting at this time the first volume, which is a synopsis of the study, that expands on the published reports in the JAMA. In addition, I am submitting the detailed analysis of the Validation Study to the Committee.

This concludes my testimony.


Vietnam
(646 Men)
Non–Vietnam
(97 Men)
Percent
0
10
20
30
ND
1
2
3
4
5
6
7
8
9
10
11
12
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14
15
16
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18
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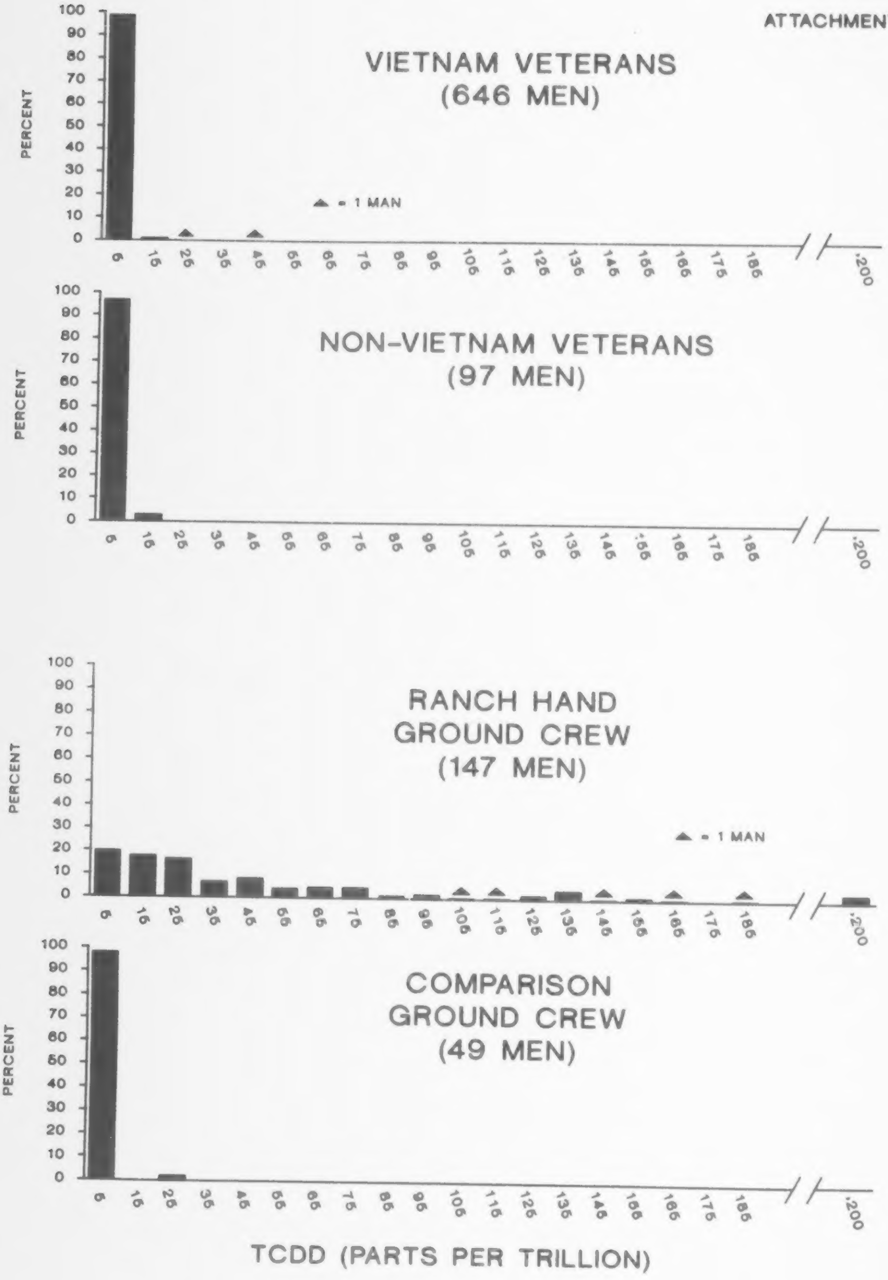
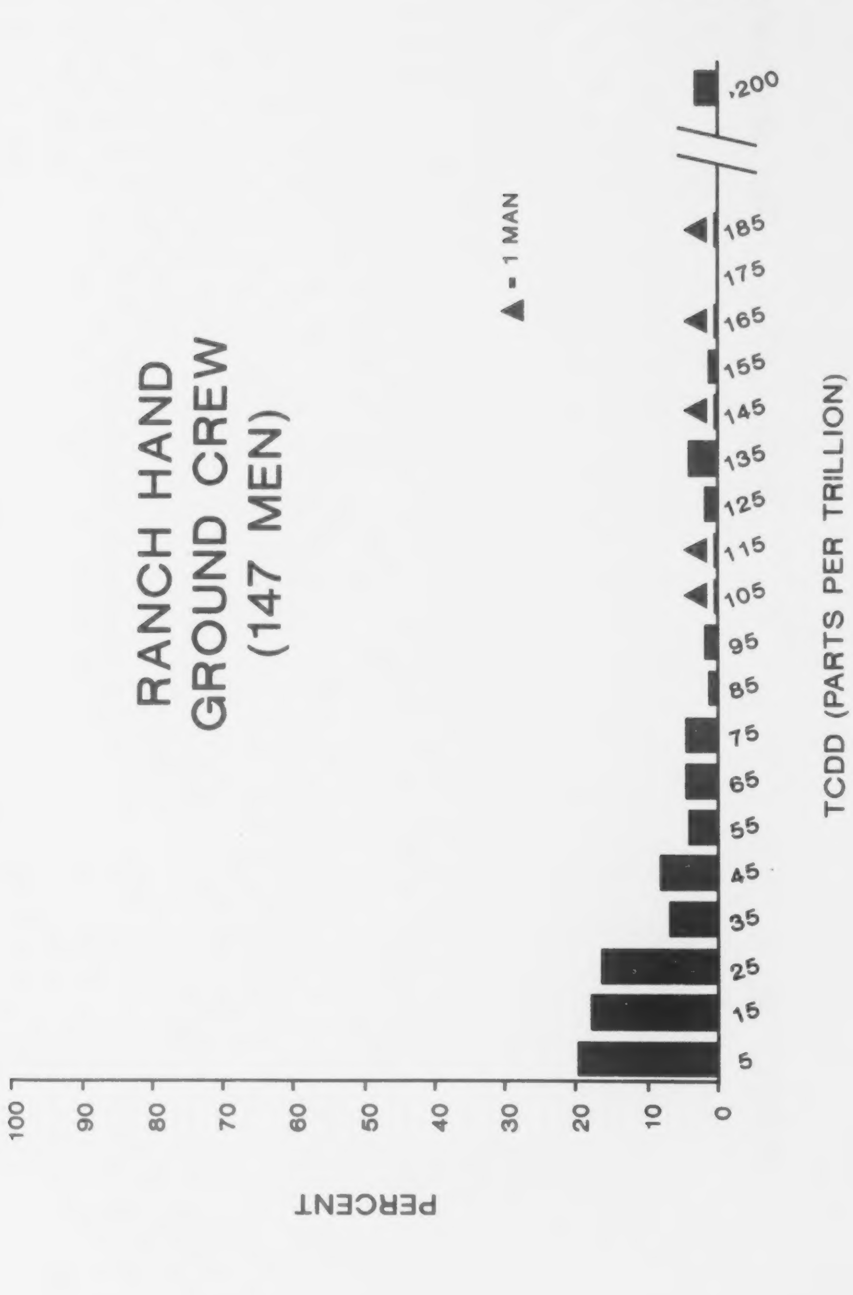
25
26
45
TCDD (ppt)
ND = Non–Detectable
▲ = 1 Man

ATTACHMENT B



ATTACHMENT C



ATTACHMENT D

Random sample of 1-tour US Army soldiers discharged at E-1 to E-5 rank.

	Vietnam	Non-Vietnam
Interviewed	7,924	7,364
Examined	2,490	1,972
Semen Analysis	324	247

Social characteristics similar (education, employment, income, marital).

Psych. prevalence: (MMPI/DIS)

	Significant differences (95% CI excludes 1.0)	
Depression	4.5%	2.3%
Anxiety	4.9%	3.2%
Alcohol abuse	13.7%	9.2%
Ever had combat-related PTSD	14.7%	(not analyzed)
Had it during past month	2.2%	(" ")

Medical history: (Reported by veterans on interview--no diff. in cancers)

"Fair/poor" health	19.6%	11.1%	
Limited activity	26.6%	21.5%	
Prescribed medications	19.1%	16.8%	
Somatic symptoms	9.5%	5.7%	
Hypertension	25.4%	20.3%	(no diff. on exam)
Benign growths	19.0%	17.1%	
Chloracne	1.4%	0.3%	(no diff. on exam)
Other skin conditions	31.2%	19.7%	(no diff. on exam)
GI ulcers	12.5%	9.8%	
Hepatitis	4.8%	3.3%	
Other liver conditions	2.7%	1.8%	
Urinary problems	15.7%	13.7%	(no diff. on exam)
Fertility difficulties	20.0%	15.5%	
(Number of children after entry into Army	1.6 <-no diff.->	1.6)	

Medical examinations: (Objective evidence--no diff. in immune system or in porphyria)

Low sperm concentration	15.9%	8.1%
Past hepatitis B infec.	14.1%	11.1%
Stool occult blood	1.3%	0.5%
High freq. hearing loss	14.4% / 18.4%	9.9% / 12.9%
	R / L	R / L

Reported birth defects in children per 1000:	64.6	49.5	*
	<--different-->		|
Major/minor defects found in birth records per 1000:	60.9	57.8	|
	<-- no diff.-->		v

* Probable under-reporting of defects by non-Vietnam group.

DEPARTMENT OF THE AIR FORCE

UNITED STATES SENATE

SUBJECT: Agent Orange

STATEMENT OF: MAJOR GENERAL ALEXANDER M. SLOAN
Deputy Surgeon General
United States Air Force

12 May 1988

Thank you for the opportunity to present an update on the progress of the Air Force Health Study of personnel exposed to herbicides in Southeast Asia.

In 1978, the United States Air Force responded to Congressional and veteran's interest in the Agent Orange issue and began work on an epidemiologic study of the possible health effects of exposure to herbicides and their 2,3,7,8-tetrachlorodibenzo-p-dioxin (referred to dioxin or TCDD) contaminants. Our study focused on Air Force veterans who served in the Ranch Hand defoliation operation during the Vietnam conflict.

In the interest of addressing the concerns of veterans, the Air Force Health Study (AFHS) was based on a scientific approach to the Agent Orange issue. The Air Force developed a protocol for a study including all 1267 members of the Ranch Hand unit serving from 1962 to 1971 and a group of matched comparisons. The comparison group was selected from the population of Air Force veterans who served in C-130 aircraft units stationed in Southeast Asia during the same time period. They were matched to the Ranch Hand group by age, race and job (pilot or copilot officer, officer navigator, non-flying officer, flying enlisted and ground enlisted). It was assumed that the comparisons were not exposed to herbicides or dioxin in Southeast Asia.

The protocol was subjected to extensive review by scientific peer groups including the University of Texas School of Public Health, the Air Force Scientific Advisory Board, the Armed Force Epidemiologic Board, the National Academy of Science and the Science Panel of the Agent Orange Working Group.

The protocol was approved in February 1981 and the first questionnaires were administered in October of that year. The baseline physical examinations were begun in January 1982 by a civilian contractor. Since that time, we have published four mortality reports and two morbidity reports. The study is a planned 20 year research effort.

What is the probability of this study to detect group differences? Power is the probability of detecting a group difference, usually expressed as a relative risk or a shift in mean values. This study has good power to detect relative risks of two or three when the disease rate in the comparison population is 5% or more. Similarly, the study has good power to detect a mean shift of 5% or more. For rarer diseases, our power is decreased. The power should improve with the passage of time since the basic disease rates should increase as the group ages.

A comprehensive clinical evaluation will be performed throughout the study with examinations by internal medicine, neurology and dermatology specialists. Psychological and laboratory testing will also be included. Participation in the study has been excellent with 87% of the invited Ranch Hands and 75% of the invited comparisons taking part in the initial evaluation; 93% of those who participated in the initial study have returned for the follow-up evaluations.

The Morbidity Report published in October 1987 found that there were some differences in subjective measures of general health in the enlisted ground personnel, but these findings were not confirmed by more objective measurements. On balance, the assessment of general health did not reveal any reason for concern in this clinical area.

No significant differences between the Ranch Hand and the comparison groups were seen in the 1987 report for skin or systemic cancers. However, when overall lifetime basal cell carcinoma rates were adjusted for risk factors involved in the cause of such cancers (e.g. geographic area of residence, skin color, skin reaction to sun) Ranch Hands had a statistically significant higher number of basal cell carcinomas than the comparisons. This type of skin cancer is the most common neoplasm in the white population in the United States, is not prone to distant spread and is usually rapidly cured with simple treatment. These cancers were found in sun exposed areas of the body.

There were no unadjusted group differences for systemic lifetime cancer in the 1987 report. However, when occupation was considered, there was a significant increase among the Ranch Hand enlisted flyers for systemic cancer. These results may be unstable since they are based on only 5 cases of cancer and even one or two additional cases would alter these findings, which do not correlate with our estimated exposure index. These men are not in the group that we think had the heaviest exposure to the herbicides in Southeast Asia. A better understanding of the relevance of this observation must await the results of the serum dioxin testing.

During the interval between the two evaluations, a single case of soft tissue sarcoma and one case of non-Hodgkins lymphoma occurred in the Ranch Hand group. Earlier similar cases were found in the comparison group. This makes the incidence of these two conditions equal in both groups.

The neurologic assessment of cranial nerve function, peripheral nerve function and central nervous system coordination, did not reveal any consistently significant group differences in the 1987 report, although abnormalities tended to aggregate in the Ranch Hands. The Babinski reflex (found adverse in the Ranch Hands at the 1982 Baseline examination) was equal in both groups at follow-up. Age, alcohol and diabetes showed classical effects with many neurological measures.

Extensive psychological testing was conducted. In general, while statistically significant differences in some portions of the testing were seen, they were quite variable in nature and their clinical relevance is unknown. Post traumatic stress disorder was evaluated and only 1% in either group had this condition. There were no group differences for current or past neuroses or psychoses. Age, educational level, and alcohol history showed strong and expected effects on the psychological measures.

Both the interval and lifetime history of liver disease were equal in both groups, as was a lifetime history of peptic ulcer disease in the 1987 report. Of the 11 laboratory tests performed to evaluate liver function, only two showed significant differences in the average values in the Ranch Hand and Comparison groups. However, the number of men who had abnormally high levels was not different in the two groups. The uroporphyrin test, which is the best indicator of porphyria cutanea tarda, was normal in the Ranch Hands. The comparisons had significantly higher levels of uroporphyrin, but this is considered to be of no clinical relevance.

In the 1987 dermatological assessment, not one case of chloracne was diagnosed on examination, nor was historical acne anatomically distributed in a pattern that suggested past chloracne in the Ranch Hand group. Exposure and comparison with the results of the 1984 report were also unremarkable.

The 1987 cardiovascular evaluation showed that when heart disease of all types was considered, the frequency of disease reached statistical significance. However, there were no group differences for hypertension or heart attacks, the types of heart disease we worry about the most. Other assessments of cardiac function by blood pressure measurements and electrocardiogram did not reveal any meaningful group differences.

Evaluation of peripheral pulses by the more accurate Doppler technique revealed group equivalence in marked contrast to the Baseline examination, which found significant pulse deficits in the Ranch Hands by manual measurement. As well, the effect of tobacco was controlled by restricting smoking for four hours prior to the measurement of the pulses. Overall, the groups were remarkably similar in cardiovascular health.

The 1987 assessment of eight hematological measures showed no significant group differences. In fact, the groups were more similar at the follow-up examination than at the Baseline examination. Age, race, and smoking were significant risk factors for most hematological measures.

The groups did not differ significantly in reported kidney disease, in the 1987 report, although the Baseline questionnaire noted such in the Ranch Hands. Five laboratory measures of renal function were similar between groups in the unadjusted analyses. No pattern of results suggested a detriment to either group in the adjusted analyses.

For endocrine function, TSH and testosterone means were significantly higher in the Ranch Hands, in the 1987 report, but these results were within the normal range. Impaired glucose tolerance tests revealed an excess in the comparison group. Examination results for past thyroid disease, thyroid and testicular abnormalities, and additional tests for cortisol level and T3 % uptake were similar in both groups. Age, race, occupation, percent body fat, and personality type were taken into account as pertinent variables. Overall, the endocrine health status was comparable in both groups.

Comprehensive immunological tests, composed of six cell surface marker studies and three functional stimulation studies showed no significant group differences in the unadjusted analyses. Age, smoking, and alcohol usage were accounted for in the analysis. The assessment of delayed hypersensitivity by skin testing was declared invalid because of excessive reader variation and shifting diagnostic criteria.

The pulmonary assessment, in the 1987 report, consisting of past history, physical examination, and x-ray results did not indicate any consistently different disease patterns in the two groups. Age and lifetime smoking history were important risk factors for most pulmonary measures.

The exposure index analyses, which were stratified by occupation, revealed sporadic differences between exposure levels; however, there were no consistent dose-response relationships that supported an herbicide effect for any clinical area.

Comparisons between the 1984 study and the 1987 findings were conducted for 19 variables, and 5 showed significant differences in the changes of the groups between the Baseline and follow-up examinations. Of these 5 variables, one (sedimentation rate) was believed to be related to a change in laboratory methods, and the other four (Babinski reflex, depression, platelet count, and manual all pulse index) were attributed to true changes over time for the groups. In comparing all results between the examinations as well as the formal longitudinal analyses, we see a subtle, but consistent decrease in group differences over the three year period.

In summary, the 1987 morbidity report concludes that there is insufficient evidence to support a cause and effect relationship between herbicide exposure and adverse health in the Ranch Hand group at this time. The study has revealed a number of minor medical findings that require continued surveillance. In full context, the results of this study are encouraging evidence that, at this time, the current state of health of the Ranch Hand participants appears unrelated to herbicide exposure in Southeast Asia. However, we still cannot exonerate the herbicide at this time.

In addition to the morbidity analyses, periodic evaluations of the death (mortality) experience of the Ranch Hand and comparison groups have been conducted and reported. Analyses have been directed at total and cause-specific death rates with adjustment for year of birth, race, rank and occupation. All reports have contrasted survival of all known Ranch Hands who had not died in combat while in Vietnam, 1257, with 6171 matched comparisons. As of December 31, 1984, the overall mortality of the Ranch Hand group (4.4%) was nearly identical to that of the comparison group (4.6%). Ranch Hand officers have experienced fewer deaths than comparison officers while more Ranch Hand enlisted personnel have died than their matched comparison, but none of these differences are significant. As of December 31, 1985, the overall Ranch Hand and comparison mortality were 4.7% and 5.1% respectively. Due to the small number of deaths that occurred during 1985, an abbreviated mortality report was published in 1986. The 1988 mortality update is currently underway and is expected to be published this summer. This analysis will include the death experience of 20,000 men (all of the Ranch Hands and all men assigned to C-130 aircraft units in Southeast Asia between 1962 and 1971.)

Recently a follow-up evaluation of the 1984 baseline morbidity report (United States Air Force Personnel and Exposure to Herbicide Orange by Richard Albanese, M.D.) evaluates the relationship between the findings of the 1984 study and a literature review of the toxicology of dioxin. The results of subsequent follow-up clinical examinations, released in October 1987, were not included in this reevaluation. Variables from 11 clinical areas were selectively evaluated in the report: weight loss, malignant disease, birth defects, neurological disease, psychological problems, liver diseases, the presence of chloracne, heart disease, immunological function, endocrine status and death. The review highlighted six clinical areas warranting more in-depth evaluation in the future. Although this report used another approach to analyzing the 1984 data, the conclusions were essentially the same as in previous reports. We can neither definitely establish nor refute a link between dioxin and disease.

There has been much controversy concerning the relationship between herbicide exposure and birth defects in children. Initial evaluation of fertility and reproductive systems found there was a significant disparity between groups for reported birth defects. We incorrectly concluded that group differences were confined to minor skin conditions. The baseline findings of over-all group differences in reported birth defects is being reinvestigated with full medical record verification of the birth defects reported on all children fathered by study participants. Over 6,000 medical records are under review. We expect to complete this analysis next summer.

Exposure Index

The initial study protocol developed an estimated exposure index that reflects the best calculation of the effective number of gallons of herbicide to which the airmen was exposed. It is based on an estimate of gallons of herbicide sprayed per month (1962-1971), the levels of dioxin contamination and the number of men assigned each month.

Individual exposure measurements could not be made. While the method used to establish the exposure index was state-of-the-art, several assumptions concerning individual work habits and circumstances had to be made.

In mid 1986, strong evidence was demonstrated by the Centers for Disease Control (CDC) and other institutions that dioxin levels could be measured in blood as well as fat tissue. The CDC demonstrated that blood levels and fat tissue appear to be equivalent. The Air Force recently concluded a collaborative study with the CDC to validate the study and estimate the half-life of dioxin in humans. This pilot study of 200 serum samples confirms clear and meaningful dioxin exposure did occur in the Ranch Hand group. The range of dioxin exposure in the Ranch Hand group (3-314 parts per trillion) is significantly higher than the control group (3-21.3 parts per trillion). A part per trillion is equivalent to one second in 32,000 years.

The distribution of dioxin levels for Ranch Hands confirms our belief that many members of this group had significant exposure to dioxin as compared to the general U.S. population and our comparison group. The serum dioxin measurement will quantify actual dioxin body burden and provides an individual exposure assessment.

The ability to improve the estimated exposure index with the serum dioxin test is a major opportunity in the scientific evaluation of the Agent Orange issue. This new serum dioxin assay will provide an accurate measure of the current body burden of dioxin. It should also be possible to estimate the half-life of dioxin in humans. Initial calculations indicate that the dioxin half-life in humans is approximately 7 years. Serum has been collected and stored from 2,010 study participants.

Within the next two years another morbidity report on the 1987 examination results, mortality reports and an expanded birth defects analysis will be completed.

We have analyzed the results of the first 5 years of our 20 year research study looking at the herbicide health question. Nearly 100 government, academic and industry scientists have guided and contributed to the study since its inception.

Our studies have not been able to establish a definitive adverse cause-effect relationship between adverse health and Herbicide Orange exposure. However, our studies identified some issues that require further evaluation.

Comments on Proposed Legislation

The Air Force and the Department of Defense object to presumption of causality in cases of lung cancer, non-Hodgkins lymphoma and certain immunosuppresent disabilities as a result of exposure to agent orange. Both S. 1787 and S. 1692 would disregard the research effort to evaluate the health effects of herbicides. Early data from the Air Force Health Study does not support the presumptions made in S. 1787 and S. 1692 of non-Hodgkins lymphoma, lung cancer and immune system suppression of significance from herbicide exposure in Vietnam.

This legislation appears to be based on a Veteran's Administration mortality study and a study of non-Hodgkins lymphoma among agricultural workers in Kansas. The scientific methods used in the VA study severely limited the ability of the study to reach any conclusions concerning causal relationships between disease and exposure. The investigators noted an increase in lung cancer cases in Marines but not in Army personnel. However, they did not take into account the effect of smoking, the primary cause of lung cancer. Their assumption that the observed deaths from malignant conditions were due to herbicide exposure is not reasonable in light of serum dioxin levels found in Vietnam veterans. A recent study by the CDC, could not demonstrate a difference in blood dioxin levels between soldiers who were exposed to herbicide in Southeast Asia and those who never served in Southeast Asia. Nor were the blood dioxin levels of the two groups significantly different from those in the general U.S. population. This finding would suggest that the exposure of most soldiers in Vietnam was not significant.

Similarly, a cause and effect relationship between non-Hodgkins lymphoma and specific chemical exposure could not be made in the Kansas study. This study used the case-control approach and has an ill-defined exposure assessment. Allegations that herbicides cause immune system suppression in humans are not supported by scientific evidence. The CDC has reevaluated the skin testing data from residents of Missouri, and found that there were no differences in immune response when quality control of the testing was applied. The Air Force has included an extensive and comprehensive evaluation of the immune system in its study and has found no differences in immune function between the Ranch Hand and Comparison groups. This equivalence in immune function is of added importance when the results of serum dioxin testing in a subset of the study group are considered. Testing of Ranch Hands and comparisons revealed a significant increase in the mean serum dioxin level in the Ranch Hand group.

Conclusions which are applicable to the Vietnam veterans cannot yet be drawn from the scientific literature. Premature conclusions or conclusions contrary to available data undermine the credibility of the research effort and its scientists. The Air Force Health Study is a necessary part of the research now being done on herbicides. The Science Panel of the Agent Orange Working Group, Domestic Policy Council, has concluded that the two studies which are most likely to answer the question of possible health effects of phenoxy herbicides are the Ranch Hand Study and the National Institute of Occupational Safety and Health Study of occupationally exposed workers.

Although the National Academy of Sciences has the competency to conduct a literature review, such an undertaking would be redundant. The Veterans Administration, through research contracts, already sponsors a continuing annual review. The VA contractor reviews all articles published anywhere in the world on the herbicides which were used in Vietnam. The tenth volume in this continuing series was published in May 1987. A new review would be a needless expenditure of government funds.
The Air Force Health Study is the premier federally funded herbicide-related study underway. Its findings are important to our veterans and to their families. With your continued support, our work will continue. I will be happy to answer any questions at this time.

[General Sloan's autobiography, which was submitted with his statement, is being retained in the committee files.]

STATEMENT OF

ADMIRAL ELMO R. ZUMWALT, JR.

BEFORE

THE SENATE COMMITTEE ON VETERANS' AFFAIRS

MAY 12, 1988

I want to thank the Committee on Veterans' Affairs and its Chairman, Senator Alan Cranston, for inviting me to testify at its oversight and legislative hearing on Agent Orange.

The political history of an issue is often very different from the scientific development of the same issue. It was years after science had proven that radiation caused physical damage to the United States Army personnel from atomic testing before political consensus in this country allowed those physically damaged from the testing to receive federal benefits. It was years after science had proven that smoking caused damage to the human lung before political consensus allowed for a warning to be printed on a package of cigarettes. Both science and politics are intertwined. At times, politics can confuse the facts.

Certainly, the advocates of the issues surrounding Agent Orange should be objective. Agent Orange, a defoliant used in Vietnam, was a mixture of 2, 4 - D (2, 4 - Dichlorophenoxyacetic Acid) and 2, 4, 5 - T (2, 4, 5 - Trichlorophenoxyacetic Acid). During the manufacture of 2, 4, 5 - T it was contaminated by Dioxin (2, 3, 7, 8 - Tetrachlorodibenzo-P-Dioxin) or TCDD. Dioxin is a compound with marked toxicity in some species of experimental animals. That finding has led to a number of scientific studies. These studies have led to a public debate and continuing scientific controversy over whether Agent Orange or its elements cause an increased risk of cancer in humans. Although there have been a number of studies analyzing whether Agent Orange causes an increased risk in cancer, there have been several studies recently which have been publicly debated.

People who contend that Agent Orange or its elements do not cause any increased risk in cancer point out that the Ranch Hand study, which involved the United States Air Force personnel who handled Agent Orange in the aircraft, did not show any increased incidence of lymphoma (a type of cancer). These advocates point out that the Dioxin content from blood samples of military personnel who were exposed to Agent Orange and a control group who was not exposed indicates Dioxin (TCDD) medians were virtually the same. These advocates argue that although the recent study done by Sheila Hoar (Journal of the American Medical Association, September 5, 1986, Volume 256, No. 9) suggests exposure to 2, 4, D increases the risk of cancer, the Kansas farmers used in the study were also exposed to other herbicides and, therefore, those other herbicides may be the cause of the cancer not 2, 4, D.

The advocates arguing Agent Orange or one of its elements causes cancer point out that some of these same studies demonstrate an increased risk of cancer from Agent Orange and the Ranch Hand study is not of significant scientific value. Although the Ranch Hand study reported no deaths due to lymphoma, there were only 1,247 personnel in the study, a statistically insignificant number since less than one such death from lymphoma would be expected. Dr. Arnold Schecter with the Department of Preventive Medicine, Clinical Campus at Binghamton of the State University of New York, urged that Dioxin (TCDD) be measured in Vietnam veterans in 1980 and 1984 noting that Dioxin levels in the veterans would decrease with time. Dr. Schecter pointed out then that eventually heavily exposed veterans will carry levels of Dioxin that are indistinguishable with the general population, and opportunities may be lost to learn about the toxicity of this material in humans and to compensate appropriately those veterans who have or will suffer Dioxin-induced injury. Dr. Schecter has analyzed the human fat tissues of the Vietnamese in Vietnam and demonstrated that the tissue samples taken in Ho Chi Minh City (formerly Saigon - whose surrounding area was heavily sprayed with Agent Orange) showed elevated levels of Dioxin (TCDD) characteristic of Agent Orange, in comparison with tissue samples taken in Hanoi (which was never sprayed with Agent Orange). Theodore Colton, ScD., of the Boston University School of Public Health, in reviewing Sheila Hoar's study (Journal of the American Medical Association, September 5, 1986, Volume 256, No. 9) found that the case control study in Kansas reported by Hoar has importance beyond its population of agricultural workers and adds to the accumulating body of evidence concerning the health effects associated with herbicide exposure in Vietnam. The Hoar study indicated that Kansas farmers exposed to herbicides more than twenty days per year had a six-fold increase of non-Hodgkins lymphoma (cancer) relative to non-farmers. Frequent users who mixed or applied the herbicides themselves had an eight-fold increase risk for non-Hodgkins lymphoma. The strongest evidence to date suggesting that 2, 4, D, one of the elements of Agent Orange, causes cancer is the Hoar study funded in part by the National Cancer Institute. Sheila Hoar points out that although there has been criticism of the study questioning the specificity of the association with 2, 4 - D with some contending that other herbicides the Kansas farmers used were also associated with excess risk of cancer, she stands by the original interpretation of the data. Her study analyzed each herbicide and insecticide type separately and controlling for the effects of 2, 4, D and with the exception of some risks associated with Triazin, the excess lymphoma (cancer) was associated with 2, 4, D. The Hoar study does provide support for concluding that non-Hodgkins lymphoma (cancer) that arises in Vietnam veterans is caused by one of the elements (2, 4, D) in Agent Orange, particularly if there is evidence of direct exposure to the herbicide.

It should be remembered that not very many months ago a $180,000,000 suit was settled between the Vietnam veterans and the chemical companies who produced Agent Orange. Proponents for the chemical companies argued that it was simply a nuisance suit that was settled for a small amount to generate some public relations value. It is doubtful that the chemical companies would have settled for any amount if their attorneys advised them that the companies had absolutely no legal or financial exposure. Regrettably, at the time the Vietnam veterans settled the $180,000,000 suit, the evidence of the Hoar study showing an increased risk of non-Hodgkins lymphoma when Kansas farmers were exposed to 2, 4 - D was not available.

Is there more evidence that there is an increased risk in cancer with exposure to Agent Orange or its elements in the future? The Center for Disease Control has been conducting epidemiologic studies of the health of Vietnam veterans that has three major components: the Vietnam Experience Study, the Agent Orange Study, and the Selected Cancers Study. The Vietnam Experience Study will evaluate the possible health effects of the general Vietnam experience. The Selected Cancers Study will evaluate the risk of contracting soft tissue sarcoma, Hodgkins and non-Hodgkins lymphomas. The Agent Orange Study will evaluate the health effects of possible exposure to Agent Orange.

There are a number of problems that have been encountered in these studies attempting to determine if Agent Orange or its elements cause an increased risk of cancer in humans. There has been difficulty with these Agent Orange studies resulting from the unexpected failure to identify large numbers of clearly exposed veterans. There has been the question of whether it is possible to identify sufficient numbers of individuals who have had sufficient exposure to Agent Orange that has the biologic plausibility of producing adverse health effects. No threshold level has yet been determined for the health effects of Dioxin (TCDD) on humans. There have been Agent Orange exposure study difficulties due to the inability to document exposure from existing military records. There has been the attempt to validate the study of military records information based on estimates of the likelihood of exposure of Agent Orange with blood evaluations of the Dioxin (TCDD). Recent results of these Dioxin evaluations show there are no differences in Dioxin levels between Vietnam veterans and a group not exposed to Agent Orange. Therefore the White House has decided that this study should not proceed since the information suggesting Agent Orange exposure in military personnel cannot be confirmed by the blood tests checking for Dioxin. (An additional problem in the analysis of the Agent Orange and its elements in causing increased risk of cancer is that to date there are inadequate tests for the evaluation of 2, 4, D carcinogenicity in experimental animals.) The overall results will now have to rely on the Vietnam Experience Study and the Selected Cancers Study.

In the first week of September, 1987, the results of the largest mortality study of Vietnam veterans yet was released finding that former Marine ground troops died of lung cancer and certain lymph cancers (non-Hodgkins lymphoma) at a significantly higher rate than Marines who did not serve in the war. This study, conducted by the Veterans Administration, examined deaths among 49,920 Marine and Army veterans who served as ground troops in Vietnam. The study stated exposure to Agent Orange was suspected though there were other possible causes. This Veterans Administration study suggests further what two civilian studies (Hoar study and Hardell study) have suggested before that there is a link between these cancers (lymphoma) and Agent Orange or its elements.

The scientific and the political battle as to whether or not Agent Orange or any of its elements caused an increased risk of cancer in the Vietnam veteran continues. Perhaps the ultimate political question may be, "Has there been sufficient scientific evidence of the adverse effects of Agent Orange or its elements for the Vietnam veterans who were exposed to those elements to receive some compensation?".

In my judgment, the Hoar study clearly establishes the carcinogenic effects of one of the principal elements used in the manufacture of Agent Orange. The recent Veterans Administration study clearly establishes Marines exposed to Agent Orange in Vietnam suffer a higher than normal incidence of cancer.

As one who shares personal responsibility for the use of Agent Orange, I believe the time has come for this country to make some compensatory amends. I hope that one of the two Bills - S. 1692, introduced by Senator Murkowski, and S. 1787, introduced by Senators Daschle and Kerry - will be enacted into law.

[An article from the Boston College Environmental Affairs Law Review entitled, "Soldier of Orange: The Administrative, Diplomatic, Legislative and Litigatory Impact of Herbicide Agent Orange in South Vietnam", was submitted and is being retained in the committee's files.]

Statement of Senator John Kerry
Senate Veterans Affairs Committee
Hearing on Agent Orange
May 12, 1988

Mr. Chairman, thank you for this opportunity to testify once again before this Committee on the subject of Agent Orange. I appreciate your willingness to hold this hearing and to consider legislation providing compensation for the victims of Agent Orange.

Last year, when I testified before this committee on Agent Orange, I stressed the importance of this issue to Vietnam veterans. It is just as important today. Agent Orange is a pressing concern -- literally a matter of life and death -- for many Vietnam veterans. The issue will not go away. It is time for Congress to address the concerns of Agent Orange victims, and to provide compensation for those who are suffering from diseases caused by exposure to Agent Orange. I hope that you will join me in leading that fight.

Mr. Chairman, Vietnam was obviously one of our most controversial wars. You were one of those who spoke out courageously against the war at an early point. Many of us joined you in that opposition. Others just as strongly supported the war and felt it was the right thing to do. There is no need to refight those battles now.

There is a need to avoid making Vietnam veterans the last victims of the Vietnam war. But our debt to Vietnam veterans should not be repaid only in rhetoric. The Welcome Home parades are important. The Vietnam Memorial is important. The parades, the concerts, the resolutions, are all important. But there is something more important than symbolism. And that is justice and fairness towards Vietnam veterans.

We now have a proposal to elevate the Veterans Administration to Cabinet-level status. Make no mistake -- I support that legislation, and I think that the symbolism and the recognition of veterans that it implies is good. But I am concerned that we are once again falling into the trap of substituting symbolism for substance.

But far more important than symbolism is the reality of how we treat our veterans who are still suffering. And I believe that it is nothing less than wrong on the facts to tell Vietnam veterans that we cannot compensate for diseases which were caused by their exposure to Agent Orange in Vietnam. It is offensive to veterans to tell them that there is not enough "scientific evidence" to justify compensation.

Mr. Chairman, as time goes on, the evidence on Agent Orange becomes stronger and stronger. That is not surprising, since we know that it takes many years for cancers and other disease to develop which are linked to Agent Orange exposure. Let me review just a few of the studies which have come out in the past few years on this subject.

In 1983, the VA Agent Orange registry found excessive cancers among Vietnam veterans of two types -- non-Hodgkins lymphomas, and cancers of the oral cavity and pharynx.

A 1983 study by the Massachusetts Agent Orange Commission found excessive numbers of soft-tissue sarcomas and cancer of the kidney among Vietnam veterans exposed to Agent Orange.

The 1984 Ranch Hand baseline study found higher amounts of skin cancers and systemic cancers, twice as many cancers of the lip, oral cavity and pharynx, and three times as many cancers of the respiratory system, chest and genito-urinary system.

A 1985 study in Wisconsin found excessive incidences of soft-tissue sarcomas among Vietnam veterans who had been exposed to Agent Orange.

A 1986 study in West Virginia found higher incidences of non-Hodgkins lymphomas, and cancers of the testes, larynx, and respiratory system among Vietnam veterans.

The preliminary results of the CDC Vietnam Experience Study released in 1987 showed excessive instances of lymphosarcomas, leukemia, and brain cancer among Vietnam veterans.

The VA Mortality Study released in 1987, a survey of 50,000 veterans, showed rates of death due to non-Hodgkins lymphoma 110% higher than normal, and deaths due to lung cancer 58% higher than normal among Marines who served in areas heavily sprayed with Agent Orange.

The 1987 Ranch Hand follow-up study showed excessive incidence of skin cancers, systemic neoplasms, lymphomas, soft-tissue sarcomas, three times as many cancers of the oral cavity and pharynx, twice as many cancers of the bronchus and lung, and three times the number of testicular neoplasms.

And the report released on the Ranch Hand study in March of 1988, at the request of Senator Daschle and myself, showed higher incidences of tumors, birth defects, psychological disorders, blood toxicity, and cardiovascular problems.

In addition, the results which have just been released this week from the CDC Vietnam Experience Study show higher incidence among Vietnam veterans of fertility problems, low sperm count, depression, alcohol problems, anxiety disorders, skin disorders, and birth defects. I hope that these results will be made a part of the record, and studied carefully.

Other studies relating to dioxin have also shown similar results. A 1986 study by the National Cancer Institute of farmers in Kansas who had been exposed to herbicides similar to Agent Orange showed an incidence of non-Hodgkins lymphoma six times higher than normal. Studies in Sweden showed incidences of soft-tissue sarcoma five to seven times higher than normal with phenoxy-herbicide exposure. And other studies have shown similar results.

So to those who say "we don't have enough evidence", I would ask -- How high does the body count have to go? How many more Vietnam veterans have to die before we have "enough evidence" to start admitting the truth and compensating veterans?

Our legislation would establish a presumption of service-connection for two of these diseases, non-Hodgkins lymphoma and lung cancer. In addition it would ask the National Academy of Sciences to review the evidence of the scientific studies and compile a list of other diseases which

which are linked to suppression of the immune system, which may be linked to dioxin or Agent Orange exposure. If appropriate, these diseases would be added and a presumption of service-connection created.

Mr. Chairman, it is important to understand how strongly Vietnam veterans feel about this subject. At Vet Centers throughout Massachusetts, and at VA clinics and hospitals, I have met with Vietnam veterans and veterans groups. And I know that Vietnam veterans feel very, very strongly about this issue. You cannot tell a Vietnam veteran that there is "not enough evidence" on Agent Orange. They know what the evidence is. For one thing, the evidence is in their own bodies, and even worse, in the bodies of their children. They have no doubt about that.

Mr. Chairman, you led the fight to gain compensation for the veterans who are victims of atomic radiation. You argued against those in the VA and elsewhere who would tell us that there is "no scientific evidence" to link radiation with cancer -- exactly the same argument they use with Agent Orange. I supported you in that fight. And last month, we won in the United States Senate.

But before we won the fight for atomic veterans, some of them had to wait 40 years or more for compensation. And many of them died before they reached that day.

We should not make Vietnam veterans wait 40 years for compensation. I hope we are not going to wait until the 21st Century to tell Vietnam veterans that the evidence is now strong enough, and we are ready to compensate them.

I know that there is still controversy about the effects of Agent Orange. There may always be controversy, just as there may always be controversy about the Vietnam war itself. But the legislation that I have introduced is an attempt to end the controversy, and put the divisions of the Vietnam war behind us.

I am not saying that the studies should stop. Studies on Agent Orange, on dioxin and on cancers should continue. But the Ranch Hand study will not be complete until the year 2002. And we cannot ask Vietnam veterans to wait any longer.

The CDC has told us that they cannot complete their study on Agent Orange, because they cannot measure the levels of dioxin in the blood of Vietnam veterans. That is perhaps not surprising, since in many cases 15 or 20 years or more have passed since the exposure to Agent Orange in Vietnam. But that does not mean that there are no lingering health effects, no diseases or damage caused by that exposure. Let us be clear on that point.

Mr. Chairman, Vietnam veterans deserve to be told the truth. I believe that just as important as compensation itself is the simple recognition and admission of the fact that Vietnam veterans and their children are suffering -- from cancers, tumors, birth defects and other conditions linked to Agent Orange. It is time that we admitted that fact as a nation. Vietnam veterans do not want any special dispensation or special treatment. They simply want the same treatment that has been accorded to every other group of veterans under the law. Where there is a medical condition caused by military service, there should be compensation.

Perhaps all of here today will not agree on whether Agent Orange caused all of the diseases I have listed. But the evidence of the Vietnam Experience Study and other studies clearly shows that those diseases are associated with service in Vietnam. And that is really the critical point. If a veteran is suffering today from a disease caused by his service in Vietnam, then he should be compensated. It is that simple. That is the way the system is supposed to work.

Mr. Chairman, I am deeply dismayed by the attitude of this Administration on the issue of Agent Orange. As with so many issues, the rhetoric is out of touch with the reality. They tell us that Vietnam veterans are "national heroes". But they continue to turn a deaf ear to Vietnam veterans who need help.

The VA continues to tell us that only chloracne, a skin disorder, is linked to Agent Orange exposure. Only a handful of veterans have been compensated even for this disease. Meanwhile, the VA itself only reviewed seven out of more than a thousand studies relating to Agent Orange before promulgating its regulations on the subject. And at the same time, they continue to tell us that "more studies are needed".

We've heard this before, Mr. Chairman. We heard it on atomic veterans. We've heard it on acid rain. We've heard it on toxic wastes. You were a leader in California, Mr. Chairman, on the issue of toxic wastes. You took a courageous stand in 1986 in support of Proposition 65, the toxics initiative in California, which would ban herbicides and pesticides very similar in their effects to Agent Orange. You have been a leader on environmental issues. And we are dealing with the same issue here.

We know what the Administration's record has been on those issues. We know what the OMB's record has been. A study released a year ago by the Harvard School of Public Health and Mt. Sinai School of Medicine, which was commissioned by the House Energy and Commerce Committee, told us that the Office of Management and Budget "has delayed, impeded, and thwarted Governmental research efforts designed to answer public demands for information on serious public health questions" -- including Agent Orange.

They concluded that "Conditions imposed by OMB during its paperwork review of a proposed NIOSH study of New Jersey and Missouri dioxin workers have substantially delayed the initiation of this study, will substantially increase contracting costs by more than $270,000, and may even totally block the completion of this important study."

We know some of the reasons for this stonewalling and foot-dragging. They are afraid of the cost. They say it will cost too much money to compensate Agent Orange victims. They are afraid of legal liability. And they don't want to admit that they were wrong.

We heard all those same arguments in the debate over atomic veterans. And we rejected them.

You put it best, Mr. Chairman, in the debate on the Senate floor last month on compensation for atomic veterans. You said, and I quote:

"I am aware of opposition to this bill from the administration and Members of this body who fear that H.R. 1811 will set a "dangerous precedent" for other groups... to press for presumptive compensation. They use the fiscal argument that the Federal Government will be held liable for millions of dollars in claims it is in no position to pay. Mr. President, this is entirely beside the point. The point is that American veterans may be suffering from the ill effects of radiation they incurred in the line of duty to our Nation. If there is a reasonable chance that their claims of service connection have some scientific basis, it is incumbent upon Congress to give them the benefit of the doubt. Mr. President, it is not our job to find excuses to deny benefits to deserving individuals. It is not our place to reject compensation for atomic veterans solely on the basis that such action may open the door for other would-be claimants to seek compensation. If atomic veterans deserve compensation, they should be granted compensation."

Mr. Chairman, I agree with every word you said in that debate. I supported you in that debate and I voted with you. I would only add that the same words apply exactly to the issue before us -- If Agent Orange veterans deserve compensation, they should be granted compensation.

I am as sensitive as any member of the Senate to questions of cost. We have estimates from CBO that our bill will cost about $100 million a year for five years. That seems like a reasonable amount to me in light of the VA's budget for fiscal 1988 of $28 Billion dollars.

But if there are better ways, more cost-effective ways to structure a bill, I am open to them. I am ready and willing to work with you and this committee to craft any legislation which will provide fair compensation to the victims of Agent Orange.

But let us do it this year. Let us do it now. It has already been over 25 years since the spraying of Agent Orange in Vietnam started in 1962. It is already 13 years since the last American troops left Vietnam. And it is already too late for many Vietnam veterans.

Mr. Chairman, you have already heard today from Admiral Zumwalt. I do not need to retell the agonizing story of the suffering caused to the Zumwalt family by Agent Orange. And you will be hearing later today from other victims of Agent Orange.

All I can ask, Mr. Chairman, is that you and this committee listen to those stories, and consider this issue in human terms. People are suffering. People are dying. That is why we are here. And we cannot be indifferent to that suffering.

Mr. Chairman, many Americans questioned the war in Vietnam. Not all of them supported it. But Vietnam veterans gave their country the benefit of the doubt. In fairness to them, and in memory of those who gave their lives, I hope that we can give them the same benefit of the doubt. I hope that we can find it in our hearts to do as much for them, as they have already done for us.

Thank you.

I would now like to introduce Chris Gregory. Chris is a Vietnam veteran from Massachusetts and someone who has been involved closely with this issue. He was formerly the Director of the Massachusetts State Agent Orange Program, and is currently with the firm of Martilla and Kiley in Boston. I have great respect for Chris Gregory and it is a pleasure to introduce him before this Committee.

STATEMENT
OF
THE NATIONAL CANCER INSTITUTE
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE

THE

COMMITTEE ON VETERANS' AFFAIRS

UNITED STATES SENATE

MAY 12, 1988

INTRODUCTION

The National Cancer Institute (NCI) has not conducted studies on Agent Orange nor on Vietnam veterans who may have been exposed to this agent. NCI has, however, conducted research on herbicide use in agriculture, right-of-way maintenance, and home lawn and garden care. Since some of the herbicides studied by NCI are common to those used in Vietnam (Agent Orange was a formulation of 50 percent 2,4,5-trichlorophenoxyacetic acid [2,4,5-T] and 50 percent 2,4-dichlorophenoxyacetic acid [2,4-D], herbicides under study by NCI), we will review the completed and ongoing NCI agricultural and related studies. Caution must be taken, however, when considering the generalizability of the results based on agricultural use to the veterans' situation. The two scenarios may differ widely with respect to formulation, dose, frequency of exposure, duration of exposure, carrier solvents, contaminants, method of application, use of protective equipment, climatic conditions, other possibly hazardous exposures and conditions, and lifestyle factors, which could affect subsequent risk in unknown ways.

U.S. COUNTY MORTALITY DATA

The NCI epidemiologic research on health effects of insecticides and herbicides and their contaminants began in 1975 with the publication of the U.S. County Cancer Mortality Maps. The maps revealed significantly elevated leukemia, non-Hodgkin's lymphoma, and multiple myeloma mortality in counties located in the central region of the U.S., primarily agricultural areas. This pattern, coupled with reports of carcinogenic activity of individual pesticides in animal studies, led NCI to initiate a series of studies to investigate the link between occupational and environmental exposures to pesticides and the development of cancer. Several of these studies have collected detailed data on the use of specific pesticides and herbicides.

KANSAS STUDY OF NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE, AND SOFT-TISSUE SARCOMA

In 1986, NCI reported results from a population-based case-control study in Kansas of histologically-confirmed incident male cases of lymphoma (170 non-Hodgkin's lymphoma and 121 Hodgkin's disease) and soft-tissue sarcoma (133 cases). At least three controls per case (a total of 948) were available for comparison. The study concluded that:

- Farm herbicide use was associated with a 60% increase in non-Hodgkin's lymphoma, but no increase of Hodgkin's disease or soft-tissue sarcoma.

- The risk of non-Hodgkin's lymphoma increased significantly with the number of days per year of herbicide exposure and time since first exposure.

- Farmers exposed to herbicides more than 20 days per year had a six-fold increased risk of non-Hodgkin's lymphoma relative to nonfarmers. The farmers in this high use category who mixed or applied the herbicides themselves had an eightfold increased risk of non-Hodgkin's lymphoma.

- The finding of lower risk among farmers who usually used protective equipment while mixing or applying herbicides is consistent with a causal association.
- The non-Hodgkin's lymphoma excess was associated with use of phenoxyacetic acid herbicides, particularly 2,4-D.
- There were few past users of 2,4,5-T among Kansas farmers and almost all had also been 2,4-D users.
- Use of 2,4,5-T alone did not appear to increase risk of non-Hodgkin's lymphoma, although the data are inconclusive because of small numbers.

IOWA/MINNESOTA STUDY OF NON-HODGKIN'S LYMPHOMA AND LEUKEMIA

An NCI population-based case-control incident study of leukemia and non-Hodgkin's lymphoma is being conducted in Iowa and Minnesota, two States with large areas devoted to corn-growing involving heavy insecticide and herbicide use. The study is larger than the Kansas study with 622 non-Hodgkin's lymphoma cases, 578 leukemia cases, and 1245 controls. Although analysis is continuing, some preliminary results are available.

- Some associations were seen between leukemia, lymphoma, and specific herbicides, particularly among the farmers who first used the herbicides 20 or more years before the study interviews.

- The use of 2,4,5-T was associated with two- to four-fold increases in risk for acute myeloid leukemia, chronic lymphocytic leukemia and non-Hodgkin's lymphoma; however, the number of exposed subjects was small and the risks were not statistically significant except for chronic lymphocytic leukemia.

- The use of 2,4-D was associated with non-significant (20-30 percent) excesses for acute myeloid leukemia, chronic lymphocytic leukemia, and non-Hodgkin's lymphoma. Two other herbicides, chloramben and trifluralin were each significantly associated with threefold increased risks of non-Hodgkin's lymphoma.

The Kansas study, which reported greatly increased risk of non-Hodgkin's lymphoma among frequent 2,4-D users, and the Iowa/Minnesota study, which had only a slight and non-significant elevation in risk for

2,4-D, appear inconsistent. However, in the Iowa/Minnesota study, information was not gathered in the interview on number of days per year of herbicide use. Since this was the variable that showed the strongest association with cancer risk in the Kansas study, its absence in the other study may account for the apparent discrepancy in results. NCI is now recontacting subjects in the Iowa/Minnesota study to obtain this crucial piece of information.

NEBRASKA STUDY OF NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE, CHRONIC LYMPHOCYTIC LEUKEMIA, AND MULTIPLE MYELOMA

Another population-based case-control study designed to investigate the role of herbicide use and other agricultural factors in cancer was recently completed in Nebraska. Analyses of interview data from 385 non-Hodgkin's lymphoma cases, 70 Hodgkin's disease cases, 56 chronic lymphocytic leukemia cases, 72 multiple myeloma cases, and 1432 controls are underway. NCI collected detailed histories of pesticide use including days per year, the variable of importance in the Kansas study. Preliminary results seem to indicate moderate increases in risk associated with exposure to the herbicides, 2,4-D and 2,4,5-T. Risk of non-Hodgkin's lymphoma increases with days per year of 2,4-D exposure, similar to the pattern in the Kansas study, but the risks are not as great.

Much more analysis of the study data is needed before interpretation of the results can be finalized. Factors to be evaluated include intensity, duration of use, application methods, use of protective equipment, effects of multiple exposures, differences in risk between men and women, and other lifestyle characteristics.

STUDIES OF NON-FARMING OCCUPATIONAL GROUPS EXPOSED TO HERBICIDES

The research projects described above have studied herbicide use primarily among farmers. The exposure information has been based on subject recall and the accuracy and completeness of memories may fade with time. Failure to accurately recall use of herbicides would tend to weaken any causal associations, but is an unlikely cause of spurious relationships. To avoid these problems, NCI has initiated two studies of non-farming occupational groups which have had frequent exposures to herbicides and for whom work records exist documenting exposures. The studies, based on prerecorded historical exposure data, should be valuable additions to herbicide research.

ChemLawn Study. One study involves a cohort of approximately 30,000 lawn care service workers employed by ChemLawn Services Corporation. These workers have much more frequent exposure to pesticides than farmers on the average and, so, will be a good population in which to further evaluate the hypotheses raised in the Kansas study. Lawn care applicators can be exposed to herbicides, specifically 2,4-D, on a daily basis throughout the growing season, which ranges from 90 to 120 days per year. The existence of records on the type of pesticides, formulation, and treatment protocols for each year and geographical location makes this population exceptionally valuable for study. The records eliminate the need to rely upon subject recall of exposure. Also, some applicators within the company have little or no exposure to herbicides which will allow evaluation of the effects of insecticides free of the effects of herbicides. Because the company began in 1969, the NCI is planning both a prospective and a retrospective study.

Currently, the NCI is abstracting the worker occupational records and the company pesticide treatment protocols. The Institute estimates that the retrospective component of the study will take approximately two more years to complete.

County Noxious Weed Departments. Employees of county Noxious Weed Departments, whose function is to eradicate difficult to control weeds, are the second occupational cohort frequently exposed to herbicides that the NCI is studying. During the growing season, the men employed in these departments have daily herbicide exposure (primarily 2,4-D) with no confounding insecticide exposure. The county offices where these workers are employed appear to have records providing remarkably detailed information on each herbicide application, including name of the applicator, date, herbicide used, formulation, dilution, gallons and acres sprayed, and climatic conditions. The NCI currently is conducting a pilot study in Kansas to evaluate the feasibility of using these records. Although the pilot study population may be small (perhaps no more than 2,000), the maximum latent period could be as long as 30 years. Because Kansas maintains a State-wide cancer registry, the population can be studied for both cancer incidence and mortality. Other States also have Noxious Weed Departments which the Institute is attempting to include in an expanded study population.

SUMMARY OF NCI STUDIES ON HERBICIDES AND CANCER

The NCI Kansas population-based case-control study found an association between agricultural herbicide use and risk of non-Hodgkin's lymphoma. Risk increased dramatically with number of days per year of herbicide exposure. Men exposed to herbicides more than 20 days per year had a six-fold increased risk of non-Hodgkin's lymphoma relative to nonfarmers. The non-Hodgkin's lymphoma excess was associated with the use of phenoxyacetic acid herbicides, particularly 2,4-D. No excess risk of soft-tissue sarcoma or Hodgkin's disease associated with herbicide use was observed.

Preliminary results from other similar studies conducted by NCI in Iowa, Minnesota, and Nebraska do not seem to confirm the same magnitude of non-Hodgkin's lymphoma risk seen in Kansas associated with 2,4-D. Smaller, non-significant risks have been observed.

The reasons for these inconsistencies are not fully understood, but may be due in part to the need for much better exposure information. To remedy this, NCI is conducting two studies of herbicide applicators for whom records documenting exposures exist. In addition, NCI is initiating a project to improve exposure assessment methods in pesticide studies.

In conclusion, the NCI Kansas study reported an association between non-Hodgkin's lymphoma and agricultural use of the herbicide, 2,4-D. Several other epidemiologic studies are underway to further investigate this association. The relevance of this finding for the Vietnam veterans exposed to Agent Orange is not known. The exposures of farmers and the Vietnam ground troops may differ widely and may affect subsequent risk of cancer in unknown ways.

TESTIMONY OF
DR. DONALD G. BARNES
ACTING DIRECTOR OF THE SCIENCE ADVISORY BOARD
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
U.S. SENATE

MAY 12, 1988

I am Dr. Donald G. Barnes, Acting Staff Director of the Environmental Protection Agency's (EPA's) Science Advisory Board, a federal advisory committee composed of independent scientists, that is charged with reviewing the scientific basis of the Agency's regulations, standards and policies. Prior to assuming this position in March of this year, I served over eight years as Science Advisor to EPA's Assistant Administrator for Pesticides and Toxic Substances. In that capacity, I have represented EPA on the interagency Agent Orange Working Group and its Science Panel since their inception in 1979. Since my arrival at the Agency in 1979, I have been involved in a wide variety of Agency "dioxin"-related activities, including the suspension of the herbicide 2,4,5-T, the National Dioxin Study, and the recently completed risk assessment of "dioxin" residues in the Midland, Michigan. In addition, I have been involved with "dioxin" matters on the international level. For example, I was a member of two World Health Organization panels: the first, on the significance of "dioxin" in human milk and the second, on "dioxin" emissions from combustion of municipal waste and sewage sludge. I am chair of a work group of NATO nations which is developing a procedure for estimating the risks associated with exposure to a wide range of "dioxins" and related compounds.

I am currently a member of an ad hoc work group at EPA that is developing an updated assessment of the Agency's 1985 risk characterization of the carcinogenicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). This particular chemical is thought to be the most potent type of "dioxin" and is a contaminant in Agent Orange.

Agent Orange is a 50:50 mixture of derivatives of the herbicides 2,4,5-T and 2,4-D. The mixture, Agent Orange, was never registered for use in the United States; however, both 2,4,5-T and 2,4-D have been separately registered. In 1978 the Agency took action to suspend the major uses of 2,4,5-T, due, in part, to the presence of 2,3,7,8-TCDD as a contaminant in the product at the low parts per million (ppm) level. All registrations for the use of 2,4,5-T were ultimately cancelled by 1985, after a protracted administrative hearing under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Although, based on available analyses, 2,4-D contains no detectable levels of 2,3,7,8-TCDD, it does contain other "dioxins" that are thought to be significantly less toxic. This herbicide is being closely examined due to other toxicological concerns. I have attached a current "fact sheet" that summarizes the Agency's position on 2,4-D.

The Agency first developed a quantitative position on the carcinogenicity of 2,3,7,8-TCDD in 1979 as a part of a Special Review (RPAR) of 2,4,5-T. In 1983, EPA held a peer review workshop in Cincinnati, Ohio to review a later and more extensive risk assessment of "dioxins", including 2,3,7,8-TCDD. This document was published in 1985 and serves as the basis of the Agency's current position on 2,3,7,8-TCDD. The 1985 analysis, which is based primarily on the results of chronic feeding studies in rats and mice, supports the conclusion that 2,3,7,8-TCDD is the most potent man-made carcinogen in rodents that the Agency has yet evaluated using its method of analyzing risk. Animal studies also show the chemical interferes with reproductive processes and causes birth defects at doses lower than any other compound we have studied.

Interpreting these data in terms of their relevance to humans, however, has been difficult. The Agency's Cancer Risk Assessment Guidelines encourage the use of all available data in assessing the potential of human risk. For 2,3,7,8-TCDD, in contrast to the case for most other chemical substances, a large amount of data exist due to the hundreds of millions of dollars which have been spent studying this compound and its properties. Despite this comparative wealth of information, there are still many unanswered questions and no clear consensus view has emerged from the scientific community. In fact, a wide range of official views on the toxicity of 2,3,7,8-TCDD currently exist. When one looks at the positions taken by various governments in North America and Europe, one finds that "levels of concern" span a range of more than 1000-fold, with EPA adopting the strictest view of the carcinogenicity of 2,3,7,8-TCDD. Within the U.S. government, EPA's position is roughly 5-fold more strict than that of the Centers for Disease Control (CDC) and about 10-fold more strict than that of the Food and Drug Administration (FDA). These positions have been arrived at independently by reputable scientists, all of whom essentially agree upon the relevant data but whose interpretations and inferences stemming from these data differ markedly.

In 1986, the Administrator asked the Office of Research and Development to take the lead in updating the Agency's position on the carcinogenicity of 2,3,7,8-TCDD, taking into account the following:

a. Any relevant new toxicity data which had become available in recent years.

b. Recent data that suggest a "background level" of "dioxins," including 2,3,7,8-TCDD, in the tissue of humans living in industrialized societies around the world.

c. The wide range of official views on the toxicity of 2,3,7,8-TCDD.

d. The apparent discontinuity between estimated human risks, projected from animal experiments, and the effects observed in exposed human populations.

An initial draft of the re-assessment document was circulated for limited peer review last fall. As a result of the comments received from peer reviewers, EPA has been redrafting the document, which should be available for review and comment by the public when it is sent officially to the Science Advisory Board later this spring. Only after reviewing both the SAB and public comments will EPA proceed to prepare a final reassessment document.

This concludes my formal testimony. If there are specific questions which I might answer for you on this topic, I would be happy to do so at this time.

United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
Washington DC 20460

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EPA

Pesticide Fact Sheet

Name of Chemical: 2,4-D
Reason for Issuance: Proposed Decision Not to Initiate Special Review
Date Issued: March, 1988
Fact Sheet Number: 94.2

1. DESCRIPTION OF CHEMICAL

Generic Name: (2,4-Dichlorophenoxy) acetic acid

Common Name: 2,4-D (includes parent acid as well as 35 ester and salt derivatives)

EPA Shaughnessy Code: 030001

Chemical Abstracts Service (CAS) number: 94-75-7

Year of Initial Registration: 1948

Pesticide Type: Herbicide, plant growth regulator

Chemical Family: Chlorinated phenoxys

2. USE PATTERNS AND FORMULATIONS

2,4-D is a systemic herbicide widely used to control broadleaf weeds. Over 1500 registered pesticide products contain 2,4-D as an active ingredient. Approximately 60 million pounds of 2,4-D (as active ingredient) are applied annually in the U.S. The majority is used to control broadleaf weeds in wheat, field corn, grain sorghum, sugar cane, rice, barley, range and pastureland.

Use Patterns:

Agricultural - Wheat, field corn, grain sorghum, sugar cane, rice, barley, soybeans, orchard crops.

Aquatic Management - Water hyacinth and Eurasian watermilfoil control in lakes and ponds where treated water is not used for domestic or irrigation purposes.

Pasture and Rangeland - Brush control.

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Home and Garden - Lawns, ornamental, turf, parks, recreation areas.

Forest Management - Brush control, conifer release, tree injection.

Types and methods of application:

Aerial and ground equipment, knapsack sprayers, pressure and hose-end applicators, and lawn spreaders.

Types of formulations:

Granular, amine and ester liquids, dust, and aerosol spray (foam).

3 SCIENCE FINDINGS

Tolerance Assessment:

Tolerances are established for residues of 2,4-D acid in a variety of raw agricultural commodities, as well as meat, milk, eggs, poultry, fish and shellfish. The tolerances, listed in 40 CFR 180.142, include residues of 2,4-D resulting from the application of the acid, salt and ester forms.

Food additive tolerances have been established for sugarcane molasses, milled fractions from barley, oats, rye, wheat, and potable water (from 2,4-D use in specific aquatic management programs).

Toxicology Summary:

Teratology Data (birth defects) - The parent acid and ester form were tested for their ability to induce birth defects in Fischer 344 rats by oral gavage. The parent acid form did not indicate a teratogenic effect up to 75 mg/kg/day (fetotoxic NOEL = 25 mg/kg/day). The ester form (2,4-dichlorophenol) did not indicate any teratogenic effect (fetotoxic NOEL = 375 mg/kg/day).

Reproduction Data - The parent acid was fed to Fischer 344 rats to measure the effect on the reproduction system. At the lowest dose tested (5 mg/kg/day), neither parent nor offspring were affected by the administration of 2,4-D. At the next higher dose (20 mg/kg/day), a decrease in maternal body weight and pup weight was observed.

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Neurotoxicity Data - The dimethylamine salt of 2,4-D was repeatedly applied dermally (skin) to Fischer CDF 344 rats to determine if such exposure on the peripheral nervous system would produce pharmacological and/or toxicological effects. No treatment-related changes in the function or structure of the nervous system were observed, although a decrease in total animal and kidney weight was noted.

Carcinogenicity Data - In separate studies, the parent acid was fed to rats (CDF(F344)/Crl-Br) and mice ($B_6C_3F_1$ Crl-Br) for 2 years to determine the carcinogenic potential of 2,4-D. The rat study found a marginally statistically significant trend for astrocytomas (brain tumors) based on an increased incidence of these tumors in male animals at the high dose group. The mouse study found no carcinogenic response. However, the rat study provides inadequate evidence of carcinogenicity in laboratory animals.

Epidemiological Data - A number of studies have been conducted to determine whether 2,4-D produces cancer in humans. A study conducted in Kansas found an apparent association between non-Hodgkin's lymphoma and farmers who used phenoxy herbicides, including 2,4-D, but found no association between soft-tissue sarcoma and Hodgkin's disease and the same farmers. The Agency has determined that this study, based on bias and confounding factors, is inadequate for assessing 2,4-D's carcinogenic potential. Another study conducted in Western Washington found no association between non-Hodgkin's lymphoma or soft-tissue sarcoma and farmers specifically handling 2,4-D. Including other studies, the available epidemiological evidence is not adequate for classifying or regulating 2,4-D as a carcinogen.

4. SUMMARY OF PROPOSED REGULATORY DECISION

Pursuant to Special Review procedures, preliminary notifications were sent on September 22, 1986 to registrants of 2,4-D and on December 3, 1986 to registrants of 2,4-DB and 2,4-DP (structural relatives of 2,4-D), informing them that the Agency was considering initiating a Special Review based on the new epidemiologic evidence.

Following a review of comments received on the preliminary notifications and a more thorough analysis of all available data, the Agency is proposing not to initiate a Special Review of 2,4-D, 2,4-DB and 2,4-DP at this time. This decison is based on a consensus of opinion from EPA scientists, epidemiological experts, and the FIFRA Scientific Advisory Panel that existing epidemiologic evidence is inadequate to regulate 2,4-D as a carcinogen.

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5. CONTACT PERSON

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Testimony of Robert W. Long, Deputy Assistant Secretary
Science and Education
United States Department of Agriculture
before the
Committee on Veterans Affairs
United States Senate
May 12, 1988

We are pleased to testify before the Senate Committee on Veterans Affairs.

The primary mission of our Agricultural Research Service is to assure an adequate supply of high quality food and fiber for the American people and for export. Our major inputs into the Agent Orange issue have been in the environmental area, particularly in the fate and behavior of 2,4-D, 2,4,5-T and the dioxin impurity TCDD in soils, plants, water, farm animals and some limited studies on worker exposure to these herbicides.

We have testified at several hearings and participated on several governmental panels dealing with concerns about Agent Orange. We have provided considerable documentation at these hearings and our research findings are published in open scientific journals. We can provide you with these materials, if they are of interest to the current deliberations.

To facilitate the hearings this morning, we would like to review with you in capsule form our involvement with these chemicals during three time segments.

1. Our early involvement with the phenoxy herbicides before the announcement in late 1969 that 2,4,5-T caused birth defects in rats and mice.

2. Our involvement from 1970 up to our previous testimony before this Committee on September 10, 1980, and

3. Our involvement since that time to the present.

1. EARLY INVOLVEMENT WITH THE PHENOXY HERBICIDES

We first did research on 2,4-D at the Beltsville Agricultural Research Center shortly after World War II. Subsequently, we examined the effectiveness of herbicide 2,4,5-T for brush control on pasture, rangeland, and rights-of-way.

Over the decade following World War II, we expended considerable research effort to examine the performance of the phenoxy herbicides in a number of agricultural cropping systems. We conducted studies on farm animal toxicology, fate of herbicides in the environment, and on the presence of herbicides in food products.

The United States Forest Service controlled vegetation in our National Forests with the phenoxy herbicides and considerably reduced our labor costs in managing these properties. Use of these herbicides also allowed us to deal economically with those areas that could not be easily managed by cultural or mechanical methods for removing unwanted vegetation.

Around 1963, we entered into an agreement with the Department of Defense, under the auspices of the Advanced Research Project Agency (ARPA Order

No. 424) to conduct research in Texas, Puerto Rico and Southeast Asia on the defoliation of vegetation in tropical and subtropical habitats. At that time, we used a mixture of herbicides containing 2,4-D and 2,4,5-T which are the herbicides in Agent Orange. We found that this mixture was extremely effective in defoliating vegetation in tropical and subtropical areas. The objective of this research was to reduce our casualties in Vietnam due to enemy ambush.

We sent observers into Vietnam during the war to observe the effects of Agent Orange and related herbicide mixtures on vegetation control. We were particularly interested in the succession of vegetation in sprayed areas and whether permanent damage had been done to the ecology in the treated areas.

2. PERIOD BETWEEN 1970-1980

The disclosure in late 1969 that 2,4,5-T caused birth defects in rats and mice and the subsequent disclosure that the 2,4,5-T samples used in these studies contained substantial amounts of the potent dioxin impurity, TCDD, responsibility for these birth defects have figured in the Agent Orange debates that have lasted almost two decades.

Our scientists attended meetings in the then Department of Health, Education and Welfare (now HHS) with the former Surgeon General Dr. Jesse Steinfelt, shortly after these disclosures. At that time, we made a commitment to learn more about TCDD, the most toxic form of dioxin found in the phenoxy herbicides.

In 1970, USDA (through the Agricultural Research Service) launched high-priority research to investigate:

(a) the amount of chlorodioxin impurities in a number of pesticides; and

(b) the distribution, fate, and potential biosynthesis of the chlorodioxins in the environment, especially in soils.

This information was needed to help assess any environmental problems resulting from application of 2,4,5-T containing TCDD on U.S. crop and forest lands.

To best accomplish these objectives, our scientists cooperated with other Federal, university, and industrial scientists. Emphasis was on free and rapid exchange of information.

The survey of pesticides for dioxin content was completed by 1972. It showed that TCDD, the most potent of the dioxin family, was found in nearly half the 2,4,5-T samples but was absent from other related phenoxy herbicides. Most of the positive findings were from one manufacturer who, by 1973, no longer produced 2,4,5-T.

Environmental testing conducted by our scientists included studies of dioxin's breakdown by sunlight, leaching in different soil types, persistence in soils, uptake by crop plants, biosynthesis within the soil, and bioaccumulation in, and toxicity to, aquatic organisms. By 1973, most results of this research had been published. In brief, the dioxin TCDD was found to be stable in the environment, with no detectable leaching, no biosynthesis in soils, and virtually no uptake by plants. Dioxin was accumulated by aquatic organisms and was very toxic to fish.

In the ensuing years, the U.S. Department of Agriculture was represented on the Veterans Administration Advisory Committee on Health Related Effects of Herbicides and on the White House Agent Orange Working Group. We also had a representative on the Scientific Panel in the White House Working Group. Our contributions were confined to environmental measurements and limited aspects of human exposure.

USDA scientists, our cooperators in the university system and agricultural trade associations were involved in several studies that were part of the total scientific effort being tracked by the White House Agent Orange Working Group. These studies included:

- o Human Exposure to 2,4-D in Field Crop Situations - ARS, USDA
- o Pacific Northwest Mothers Milk Survey - University of Washington
- o Possible Effects of Pesticide Exposure on Reproductive Mortality and Morbidity - National Agricultural Aviation Association

Reports of these studies have been published and can be made available. In the ARS, USDA study, we examined 2,4-D levels in urine collected from 26 ground applicators in North Dakota and 19 aerial applicators in Washington. The objective of this study was to measure worker exposure levels to 2,4-D under normal working conditions. Aerial applicators provided 24-hour urine samples on alternate days during a continuous spray operation. The ground applicators supplied six consecutive day samples. Without going into great detail, several trends were apparent from these studies. In the aerial applicators, the loader/mixer received a larger dose of 2,4-D than the pilot. This means that workers handling the concentrated 2,4-D solutions were receiving the greater dose. In the ground applicator studies a similar pattern was observed, although the occupational parameters were somewhat different. The dosage, as measured by urine levels of 2,4-D, increased from the applicator to the loader/mixer to the loader/mixer/applicator. This trend again reflects the greater exposure for people coming into contact with the concentrated herbicide formulation as opposed to the diluted spray solutions. There was also a correlation between the amount of 2,4-D measured in the urine and the amount applied, and with the hours of exposure for the ground workers. We could find no association with age, weight, and type of clothing for both sets of workers.

The overall objective of this survey and several others conducted by cooperators during a similar time period, was to obtain a better understanding of risk, which is a function of both exposure and toxicity. It is difficult to draw parallels between the Vietnam experience and the American agricultural use of these chemicals. It would seem reasonable to assume, based on several exposure studies conducted in the United States, that the Ranch Hand personnel in Vietnam would have experienced the greatest exposure. The Ranch Hand personnel involved in loading/mixing Agent Orange, might be the best benchmark population to monitor for health effects. This assumes a relationship between TCDD exposure and herbicide exposure.

As both of these Committees moved more deeply into birth defect studies and large-scale epidemiology studies on the health of various exposed groups, our input became more limited.

ACTIVITIES DURING THE 1980's

In the 1980's, we worked closely with the Canadian Government when it was discovered that a dioxin isomer less toxic than TCDD was detected in 2,4-D. Since 2,4-D is used extensively for weed control in wheat production, we had several meetings with the Canadians, where we shared information and discussed possible options.

We have worked closely with Dr. Aaron Blair, Chief, Occupation Studies Section, and his coworkers of the National Cancer Institute on the protocols for a study on the use of herbicides and the incidence of cancer among farmers in the State of Kansas. Results of this study were released earlier. We are now cooperating with Dr. Blair by reviewing protocols on a second proposed study involving the development of exposure assessment methods for studies of pesticides.

Our scientists have recently attempted to answer the difficult question concerning potential human exposure to TCDD and related chemicals in soil. This activity originated when other Agencies requested assistance in evaluating the TCDD episode at Times Beach, Missouri and the PBB contamination in Michigan. Much of the data we have collected is from surrogate animals and chemicals other than TCDD. Our research with animals grazing on contaminated soils shows that the major route of uptake is by direct consumption of soil. The grazing animal can take up from one to five percent soil as part of its total diet, based on a dry weight basis. The bioavailability of chemicals in the contaminated soil then is a major route of exposure to the animal and humans consuming that contaminated meat or milk product. By comparison, direct dermal contact was found to be an insignificant route of exposure when compared to consuming contaminated soil. We believe this may have some bearing on the question of exposure of our combat personnel in Vietnam when they moved into a previously sprayed area. It would appear their greatest problem would have occurred if they consumed locally grown animal products as compared to direct contact with the sprayed soil. Again the differences between the two situations are large, nevertheless the trends suggest that direct dermal contact may not be a major route of entry.

This then, in encapusulated form, covers our historical involvement with the herbicides 2,4-D and 2,4,5-T and their associated dioxin contaminants. The time is too limited for us to discuss these issues in any great detail.

We have appreciated this opportunity to appear before the Senate Committee on Veteran Affairs. We would be pleased to answer any questions relating to our testimony or supply any information available to us that the Committee may consider useful.

STATEMENT OF OLIVER MEADOWS

CHAIRMAN, VETERANS' ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS

AND

ARMON F. YANDERS, PH.D

MEMBER, SCIENTIFIC COUNCIL, VETERANS'ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS

Mr. Meadows

Mr. Chairman, it is a pleasure to appear before you today to provide you with a brief description of the activities of the Veterans' Advisory Committee on Environmental Hazards particularly as they relate to the issue of the health effects of exposure to dioxin.

As you know, the Committee was established pursuant to Public Law 98-542, the Veterans' Dioxin and Radiation Exposure Compensation Standards Act. The Committee's membership consists of 4 lay members and 11 scientific members. The scientific members serve as a Scientific Council which makes findings and evaluations regarding pertinent scientific studies relating to the adverse effects of dioxin exposure. Dr. Yanders, a member of the Scientific Council, will describe for you in greater detail the work of the Council. Let me just say briefly that the full Committee actively participates in the deliberations of the Council. The lay members are fully aware of the concerns of the scientific members regarding studies reviewed by the Council and they raise questions about studies that are of particular significance. We are fortunate indeed to have such a dedicated membership. For your information, I am attaching to my statement the Committee's roster. I think, you will be impressed, as indeed I am, with the background and expertise the various members bring to the Committee. I might add that these members have given very generously of their time and their contributions constitute an exemplary public service. None is shy about asking questions or challenging another member's statement of opinion. This has fostered full and complete debate of the many complex issues facing the Committee and has enabled the members to arrive at a consensus concerning an evaluation of a scientific paper or a recommendation to the Administrator.

Let me at this point defer to Dr. Yanders to provide you with a more focused discussion of the activities of the Scientific Council.

Dr. Yanders

It is a pleasure to appear before this committee today to provide you with an overview of the activities of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards. Let me at the outset express the regrets of Dr. Theodore Colton, the Chairman of the Dioxin Panel, who could not be here today due to other commitments. As Mr. Meadows said, the Scientific Council is comprised of eleven members with various scientific expertise. It consists of two panels, a radiation panel headed by Dr. Warren Sinclair of the National Council on Radiation Protection, and a dioxin panel chaired by Dr. Colton of the Boston University School of Public Health. Let me briefly describe for you how the Council operates and then summarize for you the consensus opinion of the Council concerning the health effects of exposure to dioxin.

Prior to each meeting, the Veterans Administration forwards to the chairmen of the two panels a number of materials for review by the Council. These come primarily from the VA's search of the scientific literature but materials may also be submitted for review from other sources as well, such as this Committee for example or from veterans service organizations which often have been requested to submit any evidence of toxicity that they may have or are aware of. The chairman of each panel reviews the materials and makes an initial decision as to whether the particular paper is relevant to the concerns of the Committee. If it is, then a determination is made by the chairman concerning the importance of the paper to the Committee's deliberations. By that I mean the chairman considers such factors as whether the paper presents new findings; whether it is a review or analysis of previously published findings; and whether the paper appeared in a peer reviewed scientific journal or in the lay press. After making an initial determination as to what materials should be considered by the Council, he then assigns one or two members of the Council to serve as reviewers. Two reviewers would be assigned if the material clearly warrants the Council's attention and one reviewer if it was of questionable value. The single reviewer would then exercise his judgement concerning the relevance of the material to the work of the Committee.

At the meeting of the Committee, the members are asked to make a brief presentation concerning their assessment of the materials assigned to them. Following each presentation there is an opportunity for comments or questions regarding the presentation and then the members arrive at a consensus concerning the relevance of the material to the veterans' concerns, whether the conclusions expressed in the material are supported by the data reported, and whether the VA should be advised to change it's compensation guidelines in light of the particular material reviewed either singularly or in the context of previously considered materials.

From time to time the Council is asked a specific question about a disease's relationship to either dioxin or ionizing radiation exposure. Essentially the same process is engaged in. The Chairman of the particular panel assigns a member to lead a discussion of the question presented, following which the Council arrives at a consensus and prepares a response with which all members agree..

The Veterans Administration has actively solicited the submission of materials for Comittee review from veterans service organizations, members of Congress, state Agent Orange programs, and interested individuals. Thus far, more than 70 papers relating to the health effects of exposure to dioxin have been referred by the Veterans Administration for the Council's consideration. The Council has reviewed in detail more than 60 of these materials with the remaining papers being considered to be of little value to the work of the Council. For your information, a listing of the materials reviewed by the Council is attached to the end of our statement.

It is the consensus of the Council that there is no convincing scientific or medical evidence to associate adverse health consequences with exposure of Vietnam veterans to dioxin or Agent Orange. In fact, the evidence is accumulating that Vietnam veterans are not at increased risk for disease. There are, however, some areas that are especially deserving of close examination; in particular, whether there is a relationship between exposure and the later development of non-Hodgkin's lymphoma. It is our understanding that the Veterans Administration is exploring a number of research initiatives that may help to resolve that issue.

Regarding the two bills under consideration, it is the consensus of the Scientific Council that the proposed legislation is not based upon sound scientific evidence. I will defer to Mr. Meadows, the Chairman of the Advisory Committee, for a more complete discussion of the Advisory Committee's assessment of this legislative proposal.

Let me conclude my formal remarks by urging that this body give very serious consideration to the scientific evidence which is currently available. While science cannot provide all the answers to all of your questions, it can, I think, be a source of encouragement in that a great deal of progress has been made and, as I indicated earlier, the answers now being learned do show that Vietnam veterans have not suffered adverse health effects as a consequence of their possible exposure to Agent Orange while in Vietnam.

Mr. Meadows

At its most recent meeting in February, the members of the Advisory Committee expressed a sense of frustration about their inability to get across the point that when all is said and done, the evidence convicting dioxin or Agent Orange is very, very weak. The scientific members also expressed frustration that science may never be able to definitively answer the question. There will always be those nagging doubts: has the right question been asked, has the right group of persons been investigated, and so forth. Nevertheless, the members believe that the Veterans Administration has embarked on the proper course and that it should remain steadfast in its efforts to address the concerns of Vietnam veterans. It should do so with integrity and with steadiness of purpose so that Vietnam veterans can believe that it truly does have their interests at heart. I think that the Congress has thus far acted in a responsible and responsive manner in addressing this highly emotional issue. Now that we have learned so much and are close to learning more, the question must be asked whether this is the right time for this type of legislative response? It is my opinion and the opinion of the members of the Advisory Committe that it is not.

VETERANS' ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS

Dioxin Experts

George D. Lathrop, M.D., Ph.D., Science Applications International Corporation, Boerne, Texas

Dr. Lathrop received his medical degree from the University of Illinois in 1962 and his doctorate in epidemiology from the University of California at Berkley in 1968. Formerly the Chief, Epidemiology Division, United States Air Force School of Aerospace Medicine, Dr. Lathrop was the chief investigator for the Air Force "Ranch Hand" study. He is a Fellow of the American College of Preventive Medicine and is certified by the American Board of Preventive Medicine. He is a member of several professional organizations, including the American Public Health Association and the Texas Society of Infectious Diseases.

Walter Melvin, M.D., Professor of Environmental Health Sciences, Colorado State University, Fort Collins, Colorado

Dr. Melvin received his medical degree from the University of Colorado in 1949, a Master of Public Health degree in industrial hygiene from the Harvard University School of Public Health, and a Doctor of Science degree in Environmental Toxicology and Occupational Health from the University of Cincinnati in 1962. He is a founding member of the American College of Toxicology, a Fellow in the American Public Health Association, and a member of a number of other professional associations.

Radiation Experts

James V. Neel, M.D., Ph.D., Professor of Genetics, University of Michigan Medical School, Ann Arbor, Michigan

Dr. Neel received his doctorate in genetics in 1939 and his medical degree in 1944, both from the University of Rochester. He served on the National Research Council's Atomic Bomb Casualty Commission. His membership in professional organizations includes the National Academy of Sciences, the Association of American Physicians, the American Philosophical Society, and the American Society of Naturalists. His principal professional interest is in the area of the genetics of man. He has had extensive experience in the area of the genetic effects of radiation.

Arthur C. Upton, M.D., Institute of Environmental Medicine, New York University Medical Center, New York, New York

Dr. Upton received his medical degree from the University of Michigan in 1946 and is certified by the American Board of Pathology. He has had extensive experience in the area of the effects of radiation exposure with particular interest in the pathology of radiation injury and endocrine glands, cancer, carcinogenesis, experimental leukemia, and aging. He was recently the Director of the National Cancer Institute.

Edward W. Webster, Ph.D., Department of Radiology, Massachusetts General Hospital, Boston, Massachusetts

Dr. Webster received his doctorate in electrical engineering from the University of London in 1946. His particular areas of interest are radiological physics, including radiation dosimetry and protection, in which he is certified by the American Board of Radiology. He is a member of a number of professional associations, including the American Association of Physicists in Medicine, the Health Physics Society and the Society of Nuclear Medicine.

Generalists

Michael Bender, Ph.D., Brookhaven National Laboratory, Upton, New York

Dr. Bender received his doctorate in biology from the Johns Hopkins University in 1956. He has had experience in the field of radiation and genetics. He is a member of several professional societies, including the American Society for Cell Biology, the Radiation Research Society and the Environmental Mutagen Society.

Theodore Colton, Sc.D., Professor of Public Health, Boston University School of Public Health, Boston, Massachusetts

Dr. Colton received his doctorate from the Johns Hopkins University in 1960. He has had extensive experience in the field of biostatistics and epidemiology. The professional organizations to which he belongs include the Society for Epidemiological Research, the American Public Health Association, and the Biometrics Society. He is a Fellow of the American Statistical Association.

Leonard T. Kurland, M.D., Dr. P.H., M.P.H., Chairman, Department of Medical Statistics and Epidemiology, Mayo Clinic, Rochester, Minnesota

Dr. Kurland received his medical degree from the University of Maryland in 1945, his master's degree in public health from Harvard University in 1948 and his doctorate in public health from the Johns Hopkins University in 1951. He is certified by the American Board of Preventive Medicine. Among his professional interests is the epidemiology of chronic disease. He is a member of the American Epidemiological Society.

Warren K. Sinclair, Ph.D., President, National Council on Radiation Protection and Measurements, Bethesda, Maryland

Dr. Sinclair received his doctorate in physics from the University of London in 1950. His professional interest is in the areas of radiation protection, radiation physics, and radiation biology. His membership in professional organizations includes the Radiation Research Society, the Society of Nuclear Medicine, and the Association of Physicists in Medicine.

Armon F. Yanders, Ph.D., Professor of Biological Sciences and Director, Environmental Trace Substances Research Center, University of Missouri, Columbia, Missouri

Dr. Yanders received his doctorate in zoology from the University of Nebraska in 1953. A geneticist and former Dean of the College of Arts and Sciences of the University of Missouri at Columbia, he is a member of the American Society of Zoologists, and the Genetics Society of America. His research has involved the genetic effects of ionizing radiation and toxic chemicals.

Lay Members

Oliver Meadows, Godley, Texas

Mr. Meadows is a former National Commander of the Disabled American Veterans and former staff director of the House of Representatives' Veterans' Affairs Committee. A disabled veteran of World War II, he currrently serves on the Administrator's Educational Assistance Advisory Committee.

Col. Eileen Bonner, Washington, D.C.

Col. Bonner is the current president of the Reserve Officers' Association. A registered nurse, she is a doctoral candidate at Columbia University and a health care administrator.

Mr. Charles F. Conroy, Jr., Agent Orange Assistance Program, Office of Community Health Services, Charleston, West Virginia

Mr. Conroy, a Vietnam veteran, is currently the Director of the Agent Orange Assistance program for the state of West Virginia. Under his direction, the state has developed a medical testing program for Vietnam veterans who may have been exposed to Agent Orange. He has been an active participant in the Veterans' Advisory Committee on the Health-Related Effects of Herbicides and will serve as a liaison between the Environmental Hazards Committee and the Committee on the Health-Related Effects of Herbicides. In addition, he has played an active role with the various state Agent Orange programs that have been established throughout the country.

Hon. Michael Zimmerman, Supreme Court of Utah, Salt Lake City, Utah

Justice Zimmerman was recently appointed to the Supreme Court of Utah. As the Governor of Utah's former representative on the Department of Energy's Offsite Dose Assessment Advisory Committee, he has a demonstrated interest in the issue of radiation-induced illnesses.

AGENT ORANGE RELATED MATERIALS

Author(s)	Article	Review Date
	Agent Orange, "Iowa Survey of Vietnam Veterans."	March 1986
	"American Legion Vietnam Veterans Study."	March 1986
	Centers for Disease Control, "Postservice Mortality Among Vietnam Veterans." JAMA 257(6): 790-795 (1987)	April 1987
	Environmental Protection Agency, "Health Assessment Document for Polychlorinated Dibenzo-p-Dioxins." (Chapter 11) (1985)	April 1987
	"Health Survey of Massachusetts Vietnam Veterans." (1986)	November 1986
	"Serum Dioxin in Vietnam-Era Veterans - Preliminary Report." Morbidity and Mortality Weekly Report, vol. 36, no. 28: 470-475 (July 24, 1987)	October 1987
Anderson, et al.	"Wisconsin Vietnam Veteran Mortality Study: Proportionate Mortality Ratio Study Results."	March 1986
Anderson, et al.	"Wisconsin Vietnam Veteran Mortality Study: Proportionate Mortality Ratio Results; Standardized Mortality Ratio Results. Final Report." (1986)	November 1986

Breslin et al.	"Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War," Veterans Administration (1987)	October 1987
Coggon et al.	"Mortality of Workers Exposed to 2 Methyl-4 chlorophenoxyacetic Acid," Scan. J. Work Environ. Health 12: 448-454 (1986)	October 1987
Cohen, Felissa L.	"Paternal Contributions to Birth Defects." Nursing Clinics of North America 21: 49-64 (1986)	February 1988
Conso et al.	"Accidental Human Exposure to Polychlorinated Dibenzofurans and Polychlorinated Dioxins Following a Transformer Fire," Chemosphere 15: 1953-1955 (1986)	Not Reviewed
Constable and Hatch	"Reproductive Effects of Herbicide Exposure in Vietnam: Recent Studies by the Vietnamese and Others." Teratogenesis, Carcinogenesis, and Mutagenesis 5: 231-250 (1985)	April 1987
Cook et al.	"Evaluation of the Mortality Experience of Workers Exposed to the Cholrinated Dioxins," Chemosphere 15: 1769-1776 (1986)	October 1987
Di Domenico and Zapponi	"2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) in the Environment: Human Health Risk Estimation and Its Application to the Seveso Case as an Example," Regulatory Toxicology and Pharmacology 6: 248-260 (1986)	October 1987

Del Corno et al.	"Problems in the Asssessment of Human Exposure to Tetrachlorodibenzodioxin (TCDD): The Marker Chloracne." Eur. J. Epidemiol. 1: 139-144 (1985)	February 1988
Erikson, Hardell, et al.	"Soft Tissue Sarcomas and Exposure to Chemical Substances: A Case-referrent Study." Br. J. Ind. Med. 38: 27-33 (1981)	June 1985
Eschenroeder et al.	"Health Risk Analysis of Human Exposures to Soil Amended with Sewage Sludge Contaminated with Polychlorinated Dibenzodioxins and Dibenzofurans," Vet. Hum. Toxicol. 28 (5): 435-442 (1986)	October 1987
Evatt et al.	"Report of the Royal Commission on the Use and Effects of Chemical Agents on Australian Personnel in Vietnam."	March 1986
Fishbein et al.	"Limitations of Health-Risk Estimates for 2,3,7,8-Tetrachlorodibenzodioxin," Chemosphere 15: 1883-1893 (1986)	Not Reviewed
Forcier et al.	"Mortality of Australian Veterans of the Vietnam Conflict and the Period and Location of Their Vietnam Service." Military Medicine 152: 117-123 (1987)	February 1988
Geyer et al.	"Bioconcentration Potential of Organic Environmental Chemicals in Humans," Regulatory Toxicology and Pharmacology 6: 313-347 (1986)	October 1987
Giri, Ashok Kumar	"Mutagenic and Genotoxic Effects of 2,3,7,8-tetrachlorodibenzo-p-dioxin, A Review." Mutation Research 168: 241-248 (1986)	February 1988

Gough, Michael	"Environmental Epidemiology: Separating Politics and Science." Issues in Science and Technology pp. 20-31 (1987)	February 1988
Greenwald et al.	"Sarcomas of Soft Tissues After Vietnam Service." JNCI 73: 1107-1109 (1985)	June 1985
Hall et al.	"The Agent Orange Controversy After the Evatt Royal Commission." Med. J. of Australia 145: 219-225 (1986)	April 1987
Hardell and Axelson	"Phenoxyherbicides and Other Pesticides in the Etiology of Cancer: Some Comments on Swedish Experiences," Cancer Prevention - Strategies in the Workplace, Becker and Coye, eds., Hemisphere Publishing Corp., pp. 107-119	October 1987
Hardell and Sanstrom	"Case-control Study: Soft Tissue Sarcomas and Exposure to Phenoxyacetic Acids or Chlorophenols." Br. J. Cancer 39: 711-717 (1979)	June 1985
Hatch and Stein	"Agent Orange and Risks to Reproduction: The Limits of Epidemiology." Teratogenesis, Carcinogenesis, and Mutagenesis 6: 185-202 (1986)	April 1987
Hoar et al.	"Agricultural Herbicide Use and Risk of Lymphoma and Soft-Tissue Sarcoma." JAMA 256(9): 1141-1147 (1986)	November 1986
Hoffman et al.	"Health Effects of Long-term Exposure to 2,3,7,8-Tetrachlorodibenzo-p-Dioxin." JAMA 255(15): 2031-2038 (1986)	November 1986

Holmes, et al.	"West Virginia Vietnam-Era Veterans Mortality Study."	March 1986
Jones and Chelsky	"Further Discussion Concerning Porphyria Cutanea Tarda and TCDD Exposure." Arch. Environ. Health 41: 100-103 (1986)	November 1986
Kang et al.	"Soft Tissue Sarcomas and Military Service in Vietnam: A case Comparison Group Analysis of Hospital Patients." J. Occupational Med. 28: 1215-1218 (1986)	April 1987
Kang et al.	"Soft Tissue Sarcoma and Military Service in Vietnam: A Case-Control Study." JNCI 79: 693-699 and Letters to the Editor (1987)	February 1988
Kogan and Clapp	"Mortality Among Vietnam Veterans in Massachusetts, 1979-1983." (1985)	June 1985
Lawrence et al.	"Mortality Patterns of New York State Vietnam Veterans." AJPH 75. 277-279 (1985)	June 1985
Laycock, David E.	"Dioxins: Assembling the Pieces." Canadian Chemical News November/December, 1986, pp. 7-12	February 1988
Lynge et al.	"The Evaluation of Trends in Soft Tissue Sarcoma According to Diagnostic Criteria and Consumption of Phenoxy Herbicides." Cancer 60: 1896-1901 (1987)	February 1988
Lynge et al.	"A Follow-up Study of Cancer Incidence Among Workers in Manufacture of Phenoxy Herbicides in Denmark." Br. J. Cancer 52(2): 259-270 (1985)	November 1986

Merlo and Puntoni	"Soft Tissue Sarcomas, Malignant Lymphomas, and 2,3,7,8-TCDD Exposure in Seveso," Lancet, December 20/27, 1986, p. 1455.	October 1987
Merlo, Puntoni, and Fini	"Soft Tissue Sarcomas in Seveso," Lancet, August 30, 1986, p. 525.	October 1987
Merlo, Puntoni, and Santi	"The Seveso Episode: The Validity of Epidemiological Inquires in Relation with the Definition of Population at Risk," Chemosphere 15: 1777-1786 (1986).	October 1987
Mofenson et al.	"Scientific Review Committee of the American Academy of Clinical Toxicology," Clinical Toxicology 23: 191-204 (1985)	Not Reviewed
Morcarelli et al.	"Clinical Laboratory Manifestations of Exposure to Dioxin in Children - A Six Year Study of the Effects of an Environmental Disaster Near Seveso, Italy." JAMA 256: 2687-2695 (1986)	October 1987
Ott et al.	"Cohort Mortality Study of Chemical Workers With Potential Exposure to the Higher Chlorinated Dioxins." Journal of Occupational Medicine 29: 422-429 (1987)	February 1988
Patterson et al.	"2,3,7,8-Tetrachlorodibenzo-p-dioxin Levels in Adipose Tissue of Exposed and Control Persons in Missouri: An Interim Report." JAMA 256(19): 2683-2686 (1986)	April 1987
Patterson et al.	"Human Adipose Data for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin in Certain U.S. Samples," Chemosphere 15: 2055-2060 (1986)	Not Reviewed

Paustenbach et al.	"A Critical Examination of Assumptins Used in Risk Assessments of Dioxin Contaminated Soil." Regulatory Toxicology and Pharmacology 6: 284-307 (1986)	February 1988
Pearn et al.	"Herbicides and Congenital Malformations: A review for the Paediatrician." Aust. Paediatr. J. 21: 237-242 (1985)	April 1987
Pratt et al.	"Adolescent Colorectal Cancer and Dioxin Exposure." The Lancet, October 3, 1987, p. 803	February 1988
Ryan et al.	"Variation of Dioxins and Furans in Human Tissues," Chemosphere 15: 1585-1593 (1986)	Not Reviewed
Schecter et al.	"Human Tissue Levels of Dioxin and Furan Isomers in Potentially Exposed and Control Patients Up to 15 Years After Cessation of 2,3,7,8-TCDD Environmental Contamination." Unpublished presentation before the American Chemical Society National Meeting. (1986)	November 1986
Schecter et al.	"Chlorinated Dioxins and Dibenzofurans in Human Tissues from Vietnam, 1983-84," Chlorinated Dioxins and Dibenzofurans in Perspective, Rappe et al., eds., Lewis Publishers pp. 35-50 (1986)	Not Reviewed
Schenker and McCurdy	"Pesticides, Viruses, and Sunlight in the Etiology of Cancer Among Agricultural Workers," Cancer Prevention - Strategies in the Workplace, Becker and Coye, Hemisphere Publishing Corp. pp. 29-39	Not Reviewed

Sharp et al.	"Delayed Health Hazards of Pesticide Exposure." Ann. Rev. Public Health 7: 441-471 (1986)	February 1988
Sielken, R. L.	"Quantitative Cancer Risk Assessments for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD)," Fd. Chem. Toxic. 25: 257-267 (1987)	Not Reviewed
Silbergeld and Mattison	"Experimental and Clinical Studies on the Reproductive Toxicology of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin," American J. Indust. Med. 11: 131-144 (1987)	Not Reviewed
Smith et al.	"Soft-tissue Sarcoma and Exposure to Phenoxy Herbicides and Chlorophenols in New Zealand." JNCI 73: 1111-1117 (1984)	June 1985
Smith and Pearce	"Update on Soft Tissue Sarcoma and Phenoxyherbicides in New Zealand," Chemosphere 15: 1795-1798 (1986)	October 1987
Stanley et al.	"PCDDs and PCDFs In Human Adipose Tissue from the EPA FY82 NHATS Repository," Chemosphere 15: 1605-1612 (1986)	Not Reviewed
Stehr et al.	"A Pilot Epidemiologic Study of Possible Health Effects Associated with 2,3,7,8-Tetrachlorodibenzo-p-Dioxin Contaminations in Missouri." Arch. Environ. Health 41: 16-22 (1986)	November 1986
Tschirley et al.	"Dioxin," Scientific American 254: 29 et seq. (1986)	March 1986

Vineis, et al.	"Phenoxy Herbicides and Soft-Tissue Sarcomas in Female Rice Weeders, A population-based Case-referent Study," Scan. J. Work Environ. Health 13: 9-17 (1986)	October 1987
Webb et al.	"The Diagnosis of Dioxin-Associated Illness." Am. J. Prev. Med. 2(2): 103-108 (1986)	April 1987
Weerasinghe et al.	"Levels of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (2,3,7,8-TCDD) In Adipose Tissue of U.S. Vietnam Veterans Seeking Medical Assistance," Chemosphere 15: 1787-1794 (1986)	October 1987
West and Leon	"Health Needs of the Vietnam Veteran Exposed to Agent Orange." Nurse Practitioner 11: 33-40 (1986)	April 1987
Winkler et al.	"Letter to the Editor re "Follow-up Chest Radiographs in Vietnam Veterans: Are They Useful?" Radiology 163: 583 (1987)	October 1987
Wolfe et al.	"Project Ranch Hand II, An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides, Mortality Update." (1985)	March 1986
Wolfe et al.	"Project Ranch Hand II, An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides, Mortality Update." (1986)	April 1987
Wolfe et al.	"Air Force Health Study: First Follow Up Morbidity Study." October 1987	February 1988
Woods et al.	"Soft Tissue Sarcoma and Non-Hodgkins Lymphoma in Relation to Phenoxy Herbicides and Chlorinated Phenol Exposure in Western Washington." JNCI 78: 899-910 (1987)	April 1987

The statements of the Vietnam Veterans of America (VVA) and the response of the Veterans' Advisory Committee on Environmental Hazards are as follow:

"(1) As stated above, the VA Advisory Committee, which was charged to review the pertinent scientific studies relating to the health effects of exposure to herbicides containing dioxin, reviewed as a group only a total of seven studies before recommending to the Administrator that the VA should not grant service connected status to veterans for any Agent Orange related disabilities except for chloracne."

Public Law 98-542 set forth very specific time periods within which the Agency had to promulgate final regulations. The Committee held its first meeting in April 1985 (coincidentally, the same date as the publication of the notice of proposed rule making). At its first meeting, the Advisory Committee received an orientation and overview of the issues of Agent Orange and ionizing radiation resulting from the detonation of a nuclear device. As soon as was feasible thereafter the Committee held its second meeting for the purpose of reviewing the regulations as required by section 5(c)(1) of Pub. L. 98-542. To perform that function, the members of the Committee, who were selected for membership because of their professional expertise and knowledge, need only have brought to bear their knowledge and experience in providing advice on the proposed regulations. Subsequent to the June 1985 meeting at which it specifically reviewed seven papers, the Committee has reviewed an additional 56 papers and has continued to endorse the position of the VA as contained in the governing regulations.

It should be noted that the VVA incorrectly assumes that the Scientific Council and the Committee were required by the Act to review, collegially, all pertinent scientific studies prior to the time that the final rules were issued. Under the Act, the Committee performs several distinct functions: (1) the Committee reviews regulations based upon the knowledge and experience of the members; (2) the Committee recommends appropriate administrative and legislative action; and (3) the Council reviews and comments upon the emerging scientific studies that the Council deems to be relevant. Under the Act, the Committee and the Council were not required or expected to review all the studies prior to the Agency's promulgation of regulations. Given the time available in which to review the regulations, the breadth of that task, which included both dioxin and ionizing radiation regulations, and the busy schedules of the members of the Committee, it was not feasible for the Council to review more studies prior to the time the final regulations were published.

"2. The VA did not provide the Committee with adequate administrative or financial support to conduct a thorough review of the scientific studies. From the beginning, the Committee was set up to meet once or twice a year, not nearly enough time to do a thorough review of the scientific literature. There are over one thousand scientific studies pertaining to the health effects of exposure to dioxin."

This allegation misconstrues the role of the Scientific Council and the Committee as requiring that they conduct a "thorough review" of all scientific studies pertaining to the health effects of exposure to dioxin. In fact, the Committee and the Council have discretion to select which studies to review. Adequate administrative and financial support has been made available to support the review of studies selected by the Committee for evaluation.

"3. Prior to the adoption of the final regulations, the Scientific Council of the Committee did not submit any reports to the VA on the pertinent scientific studies related to dioxin, as it was required to do."

Pub. Law 98-542 contains no requirement that the Scientific Council submit a report to the VA on pertinent scientific studies prior to the time of the adoption of the final regulations. Section 6(d)(3) of the act requires only that the Council submit "periodic reports" on its findings with regard to pertinent scientific studies reviewed to the Administrator and the Committee. Due to time constraints and scheduling difficulties, the Council could specifically review only a limited number of studies prior to the implementation of the final regulations. Moreover, prior to the promulgation of the final regulations, the Council did provide reports on its review of studies in the form of summary minutes.

"4. Neither the VA nor the Committee has enunciated a standard of proof by which the studies should be evaluated: that is, there is no clear directive to the Committee as to how much evidence is enough to warrant recommending compensation for a specific disease."

38 C.F.R. § 1.17 and §3.311a(a)(3) and (4) set forth the guidelines by which the Agency will determine whether there is sufficient evidence of a causal association between exposure to herbicides containing dioxin in Vietnam and adverse health effects. The question of "how much is enough" is one which is extremely difficult, if not impossible, to answer objectively. A variety of generally accepted factors relating to the scientific or epidemiological validity of evidence are considered by the expert Committee members, some perhaps giving more weight to one factor than others would. By engaging in educated discourse, the considered judgement of the Committee as a whole is arrived at thereby reducing the likelihood of error in judgment. The members rely on their professional judgment in making recommendations which the VA may choose to accept or reject.

"5. The VA and the Committee are using a strict 'cause and effect' test by which to judge whether or not a disease should be granted service connection based on exposure to Agent Orange; that is, unless and until the science shows that dioxin causes a specific disease in humans, compensation will not be granted. This test is being used despite the fact that other diseases have been granted service connection status without proof of a cause and effect relationship (i.e., multiple sclerosis).

Neither the VA nor the Committee is applying a "strict" cause and effect test. Instead, in accordance with the Act, we are attempting to bring to bear sound scientific and medical evidence in determining whether exposure in Vietnam to herbicides containing dioxin is causally linked to long term adverse health effects in veterans, i.e., whether a present disease was incurred in or aggravated by service. This involves a consideration of accumulating scientific evidence under recognized epidemiological principles to determine if there is a statistically significant and epidemiologically valid correlation between exposure and subsequent health effects which would be acccepted as evidence of a causal association.

The existing presumptions are largely of statutory origin and were based upon criteria of the Congress' choosing. A sound scientific and medical basis for presumptions relating to dioxin exposure is required by the Act. Other presumptions, created by Congress rather than the VA, may be based on other considerations in determining whether a particular disability should be considered to have been incurred in or aggravated by military service. For example, multiple sclerosis occurring within seven years of service is presumed service connected because Congress made a determination that scienticfic evidence on the course and development of the disease indicated that it would have started while the veteran was actually in service and therefore would have been incurred in service. It should be noted that Vietnam veterans who have any of the diseases currently covered by the statutory presumptions are already entitled to the benefit of those presumptions.

"6. The VA Advisory Committee failed to keep accurate and complete minutes of the matters discussed at the meetings."

Tape recordings exist for all meetings beginnning with the June 1985 meeting and verbatim transcripts have been prepared from those tapes. A verbatim transcript of the first meeting held in April 1985 exists for a portion of that meeting. In our view, comparison between the transcripts and the summary minutes reveals that the minutes fairly and accurately represent the matters discussed. The minutes of each meeting have been reviewed and approved by the members of the Committee.

"7. The VA failed to make the evaluations of the findings of scientific studies as required by the Act and to publish such evaluations in the Federal Register."

Evaluations were published in the Federal Register on March 11, 1987. It is anticipated that a second set of evaluations will be published during the summer and a third set will follow in the fall.

"8. The VA did not abide by the policy that reasonable doubt be granted in favor of the veteran in promulgating its Agent Orange regulations."

It has long been the policy of the VA, embodied in 38 C.F.R. § 3.102, to resolve reasonable doubt in claim adjudication in favor of the claimant. Pub. Law 98-542 required the VA to apply this policy in adjudication of individual claims based on exposure to herbicides containing dioxin or to ionizing radiation. In issuing regulations implementing Pub. Law 98-542, the VA included in both its dioxin and radiation claim regulations a provision confirming the application of the section 3.102 reasonable doubt policy in the resolution of any issue material to the determination of a claim under 38 C.F.R. § 3.311a (based upon dioxin exposure) or § 3.311b (based upon radiation exposure). The Agency also made a minor change in section 3.102, reflecting the terms of the statute, to make clear that the reasonable doubt doctrine applies where there exists an approximate balance of positive and negative evidence. We believe these actions fully satisfy the requirements of Pub. Law 98-542 regarding reasonable doubt. We do not believe the statute can be fairly interpreted as requiring application of the policy of reasonable doubt in rulemaking. In any event, however, we are not aware that an approximate balance of positive and negative evidence exists or has existed with regard to any issue relating to the VA's regulations governing claims based upon exposure to herbicides containing dioxin.

MAY 1988

TESTIMONY OF HELLEN GELBAND, SENIOR ANALYST
OFFICE OF TECHNOLOGY ASSESSMENT
U.S. CONGRESS
BEFORE THE SENATE COMMITTEE ON VETERANS' AFFAIRS

REVIEW OF OTA VETERAN-RELATED ACTIVITIES WITH SPECIAL REFERENCE TO THE PENDING AGENT ORANGE DISABILITY BENEFITS LEGISLATION

May 12, 1988

I am Hellen Gelband, a Senior Analyst at the Office of Technology Assessment (OTA) with primary responsibility for issues related to veterans' health. I am pleased to appear before this committee to offer OTA's perspective on the scientific evidence linking Agent Orange exposure in Vietnam to the health effects mentioned in the veterans' disability benefits legislation under consideration.

Since passage of Public Law 96-151 in 1979, OTA has been one of several groups reviewing and attempting to interpret the evidence concerning potential adverse health effects of Vietnam service, and particularly, of exposure to Agent Orange. We have carried out the statutory responsibilities mandated in PL 96-151 and subsequent laws--reviewing protocols for mandated studies and monitoring their conduct. Over the past eight years we have also, at the request of this committee and of the House Veterans' Affairs Committee, formally reviewed most of the major studies of Vietnam veterans and of chemical and herbicide exposures that have bearing on the Agent Orange issue. Today, I would like to present an assessment of the scientific evidence relating the conditions being considered for disability benefits--non-Hodgkins lymphoma (NHL), lung cancer, and disease-causing immunosuppressive effects--with exposure to the elements of Agent Orange. First, however, I would like to discuss what is currently known about exposure to herbicides of those who served in Vietnam.

Exposure to Dioxin-Containing Herbicides in Vietnam

PL 96-151 mandated a study of the long-term health effects of Agent Orange exposure among ground troops in Vietnam. At the time the law was written, the belief was widespread that, given the millions of gallons of Agent Orange sprayed and smaller amounts of other dioxin-containing herbicides, just being in Vietnam must have guaranteed significant exposure. When CDC assumed responsibility for the study in 1983, a major concern in the design was whether it would be possible to identify enough unexposed ground troops with whom the exposed could be compared.

In the painstaking process of examining spray records and troop movements, carried out by the U.S. Army and Joint Services Environmental Support Group (ESG), a more complex picture began to emerge. First, the uncertainties inherent in developing an exposure index from military records became clear: while it was possible to define approximately at least one daily position for most military units in Vietnam, some or all of the troops might actually have been many kilometers from that position at various times during the day. It would never be possible to determine the locations of individual men in the field. The records do not contain that level of detail, and the best research cannot compensate for that lack.

If it had been the case that the general areas occupied by troops were constantly sprayed with Agent Orange by Operation Ranch Hand while troops were present, the inability to locate ground troops precisely would be of lesser consequence. But, in fact, spraying was not constant, as the defoliation caused by a single spray or series of sprays lasted many months. While the heavily-sprayed areas may have had many separate applications, many areas were sprayed far less frequently. It appears, therefore, that direct exposure during or shortly after Ranch Hand spraying would have been relatively rare among ground troops. Whether significant exposure could occur by being in an area days, weeks, or months after spraying was unknown, and still is, to some extent. However, based on the amount of spray that was likely to have reached the ground, and on what is known of the environmental fate of the herbicide components, including dioxin, it appeared unlikely that significant exposure would have occurred in that way. The remaining uncertainty could not be resolved through more records research, however.

It then became more important to seek information about non-Ranch Hand uses of Agent Orange to which ground troops might have been exposed. It is known that herbicides were sprayed around base perimeters by Army helicopters, by truck-mounted sprayers, and by men with backpack sprayers, and riverbanks were sprayed from boats. Though these activities used only a small percentage of the total Agent Orange used, it was possible that they resulted in more direct exposures to ground troops than did Ranch Hand sprays. The ESG documented large numbers of these other sprays, but many were not recorded anywhere, and individual sprayers were not always identified in company records.

Many uncertainties remained, but a picture began to come into focus. The best evidence suggested not ubiquitous exposure, but possibly significant exposure to a relatively small number of men. In addition to the clearly exposed Ranch Hands and chemical corpsmen, there were undoubtedly others who had sprayed base perimeters or who had directly handled herbicides in other ways. Some bystanders were probably exposed directly during these operations. Even knowing that contact with Agent Orange occurred, however, it was impossible to define what might constitute a "significant" exposure.

CDC was then confronted with the apparent infeasibility of using military records alone to identify a large group of ground troops with unequivocal Agent Orange exposure, as well as doubt that a large percentage of ground troops had had significant exposure. To verify the suspected lack of correlation of military records-based exposure estimates with actual exposures, and to learn about relative levels of exposure, CDC undertook its "Comparison of Serum Levels of 2,3,7,8-TCDD With Indirect Estimates of Agent Orange Exposure in Vietnam Veterans," referred to as the "validation study." This study capitalized on new technology to measure dioxin levels in blood serum, which appears to be a reliable indicator of current dioxin body burden, and which, at least at the group level, correlates with heavy past exposures, even those many years previous.

The validation study results showed no overall differences between Vietnam veterans and non-Vietnam veterans in average dioxin levels and in the distribution of levels. In both groups, the levels are generally within the "background" range expected in the U.S. population. The rankings resulting from five different methods of classifying exposure used within the Vietnam veteran group were not mirrored in gradations of dioxin levels: for each method, men classified as likely to have had higher exposures did not have higher dioxin levels. Two Vietnam veterans out of 573 completed tests had dioxin levels of 25 and 45 parts per trillion (ppt), somewhat above the level of 20 ppt that CDC has estimated as the upper limit of "background." Neither of these men had a "high" exposure ranking. None of the 88 tested non-Vietnam veterans had a level above 20 ppt, the highest being measured at 15 ppt.

In contrast to the ground troops tested, a group of 30 Ranch Handers with known direct exposure to Agent Orange during the same time period in which the ground troops served, had much higher levels. About half of them had levels greater than 100 ppt, and several were above 300 ppt. The recent New Jersey Agent Orange Commission study also found persistent high levels in men who had handled herbicides.

This is the evidence that exists to date. At least some of the men who handled herbicides regularly were exposed to a degree that they retain elevated levels of dioxin in their bodies. Fuller information on dioxin levels in the main group of these men, the Ranch Hands, will come from the Air Force, should they proceed with their plan to determine levels for participants in the Air Force Health Study. Based on current evidence, it appears that few ground troops have elevated levels of dioxin in their bodies. The ground troops tested may not be representative of all ground troops, but CDC, in its validation study, did attempt to identify men in highly-sprayed areas who had the greatest potential for exposure. The general dioxin profile of this group was identical to that of men who had not been in Vietnam. There is, of course, no guarantee that exposure would have to have been so high as to result in a currently elevated body burden for some long-term health effect to result. The lack of elevated levels does diminish the expectation of such a finding, however, and forces greater reliance on the epidemiologic data for inferences about health effects.

Non-Hodgkins Lymphoma

In this section, and the subsequent sections on lung cancer and disease-causing immunosuppressive effects, I will review the epidemiologic evidence relating these conditions to exposure to the elements of Agent Orange, and I also will discuss the evidence from studies of Vietnam veterans, whether or not Agent Orange exposure is known.

In the late 1970's, case-control studies from Sweden produced the first evidence that exposure to phenoxy herbicides might cause cancer in people. Malignant lymphomas and soft-tissue sarcomas (STS) were found to be associated with long-term use of these materials by forestry workers. These studies alerted the scientific community, and many studies around the world followed. Such studies as these, including the original Swedish studies, are difficult to carry out for several reasons. For one thing, the cancers are relatively rare, and finding enough cases to study can be a problem. Without a large enough study population, even a moderate risk can go undetected. Second, and the factor drawing most criticism to these studies, is their imprecise measures of exposure. They rely heavily on recall of chemical use ten and twenty years earlier, and often the actual cases and controls are deceased, forcing reliance for information on a third party. The biases introduced by these problems could push the results either way--toward detecting a spurious association, or toward missing an effect that is really present.

The studies appearing in the 1980's have had mixed results. A New Zealand study of agricultural workers found no association of lymphomas or STS with phenoxy herbicides. In the United States, the two studies with greatest relevance examined the relationship of NHL to herbicides and other chemicals in those exposed occupationally.

The first, a study in Kansas, was designed to find out whether the use of herbicides by farmers increased the risk of developing STS, Hodgkins Disease (HD), or Non-Hodgkins lymphoma (NHL). In all, the study included 139 cases of STS, 132 of HD, and 173 of NHL diagnosed among white adult males from 1976 through 1982 in the state of Kansas. The control group comprised three subjects matched to each case on vital status (alive or dead) and age within two years, from the general population of white males in Kansas. Summarizing, the authors found no evidence for increased risk of STS or HD with either herbicide or insecticide use. The risk of NHL, however, was about twice as high among all herbicide users as the NHL risk in unexposed men. 2,4-D was the phenoxy herbicide most frequently reported in this population. Many of the farmers in the study also used other herbicides, including uracils, triazines, amides, and others. While 2,4-D was the exposure of interest in this study, and the most common, it was not the only one, and it is possible that the association with NHL is a consequence of one or more of the other herbicides. It is not possible to disaggregate the effects of single herbicides in this population because exposures to only one chemical were rare.

The second study came from Washington State. Its purpose was to investigate possible associations between STS or NHL, and known or inferred occupational exposure to two classes of chemicals, chlorophenols and phenoxy herbicides. Men with NHL or STS aged 20 to 79 who were reported to a registry covering western Washington State during the period 1981 through 1984 constituted the pool of cases for the study. Controls were selected from the general population of men in the same geographic area (by a combination of methods), in the same age frequency distribution as the NHL cases. A total of 128 STS cases (97 living, 31 dead), 576 NHL cases (402 alive, 174 dead), and 694 controls (475 living, 219 dead) made up the study population. The main aggregate analyses broke the potential exposure experiences for each category of chemical into categories of high, medium, low, and none. In those analyses, no significantly elevated risks were found for either STS or NHL.

In an additional analysis, a slightly elevated risk (odds ratio = 1.33) of NHL was detected for those reporting farming as an occupation, and among men who reported spraying forests with herbicides at some time. The increases are modest, and could be due to any number of factors associated with farming. The lack of association overall of NHL with what were considered high levels of potential exposure leaves considerable doubt that chlorophenols or phenoxy herbicides alone were responsible for the excess, but that possibility still exists.

A statistically significant excess of NHL among Marines is reported in the VA's "Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War." In that study, the proportions of deaths from different causes in a sample of deceased Vietnam veterans were compared with the corresponding proportions in a sample of deceased veterans who served during the Vietnam era but not in Vietnam. In Army veterans, a slight deficit of NHL, though not statistically significant, appeared. No information on exposures of any kind, either from military or civilian life, is available to guide interpretation of this study. There is no a priori reason to believe that the excess is due to Agent Orange, particularly in light of the results for the Army. The Marine finding is based on a total of 35 deaths from NHL among Marines, which represents about twice the proportion of deaths expected from the Vietnam-era Marines. This is not a large number, nor is the result so extreme as to be alarming, particularly as a result of a proportionate mortality study design, which has inherent limitations and can produce spurious results. However, as stated in OTA Director Gibbons' letter of October 23, 1987, to Chairmen Cranston and Montgomery regarding this study, we believe that this finding "should be taken seriously and that follow-up work be done to investigate possible explanations."

We understand that VA has been obtaining information to carry out some additional analyses suggested by OTA and other review groups. In our view, however, the most important piece of information will come from the NHL portion of CDC's Selected Cancers Study. Even though that study is slated to continue accruing cases through 1988, it should be possible to examine the NHL data now. Of the cancers in the study, more cases of NHL were expected than of any other type (three times the number of soft-tissue sarcomas), therefore there should be a large enough number of NHL cases already accrued for a reliable analysis. In fact, even if no more cases are added from this point on, to our knowledge, CDC's is the largest NHL case-control study ever undertaken. Information on a wide range of risk factors for NHL will be generated by this study, and it may help put together the fragmentary picture that now exists regarding NHL, occupational exposures to herbicides and other chemicals, and the risks for veterans. While that study will undoubtedly leave many questions unanswered, the information it does produce will be of tremendous value in interpreting what now exists.

Lung Cancer

We are aware of no reliable evidence linking phenoxy herbicides or dioxin to lung cancer. The VA mortality study, discussed above (see NHL) reported finding about a 50 percent excess in the proportion of lung cancers in Marine Vietnam veterans. This finding is based on 130 lung cancer deaths. The Army Vietnam veterans showed no excess. Cigarette smoking is the most obvious potential cause of the excess lung cancer deaths. It would be logical to examine this possibility before searching for less plausible connections. OTA Director Gibbons commented on this in his October 23, 1987, letters to Chairmen Cranston and Montgomery stating that "it is essential that smoking histories be obtained for these cases, and even more importantly, that information about smoking rates of Marines and other servicemen who did and did not serve in Vietnam be gathered."

Disease-Causing Immunosuppressive Effects

We know of no studies relating diseases of immunosuppression with exposure to phenoxy herbicides or dioxin. In part, however, this may be because no such group of diseases, other than a few conditions associated with severe immunosuppression, is easily identifiable. A number of studies have, however, examined various laboratory measures of immune function. Children living in the area around Seveso at the time of the dioxin release there in 1976 have shown no immunologic deficits. No differences in immunologic function between Ranch Hands and their comparisons have been noted after extensive testing. CDC's Vietnam Experience Study, which also employed an extensive battery of immunologic measurements, also found no differences between Vietnam and Vietnam-era veterans.

The one study to date that has reported finding an immunologic deficit is of the residents of a heavily dioxin-contaminated trailer park in Missouri. In that CDC study, many laboratory measurements were made, with no significant differences noted between the exposed and controls. However, in a test for general immunologic reactivity, more of the exposed than control individuals lacked a response to immune stimulants. This result is difficult to interpret, particularly since there had been some problems with interreader variability in scoring the tests. There were no differences in immune-related disease patterns between the two groups.

Summary

A great deal of progress had been made over the past few years in redefining and clarifying the question of exposure to Agent Orange in Vietnam. Current efforts, including the continuing Ranch Hand Air Force Health Study and its upcoming serum dioxin measurements, and studies reported to be under way by the New Jersey Agent Orange Commission, will help to further define a possible exposed population.

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The scientific information that now exists is insufficient to draw connections between NHL, lung cancer, and disease-causing immunosuppressive effects of exposure to phenoxy herbicides or dioxin. The information base for NHL will be greatly increased by the results of CDC's case-control study. The case for lung cancer is weak and unlikely to be strengthened by further evidence. Continued study of heavily dioxin-exposed populations may or may not reveal immunologic abnormalities in laboratory measurements and in related clinical disease, but current information is insufficient to support either conclusion at this time.

STATEMENT OF JOHN F. SOMMER, JR., DIRECTOR
NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
BEFORE THE COMMITTEE ON VETERANS AFFAIRS
UNITED STATES SENATE
MAY 12, 1988

Mr. Chairman and Members of the Committee:

The American Legion takes this opportunity to thank you for scheduling this oversight and legislative hearing on the issue of Agent Orange.

Many things have transpired since the last hearing on this important issue was held, yet little progress has been made in determining the long-term health effects of exposure to Agent Orange on Vietnam veterans.

We will first address the legislation that has been scheduled for deliberation today, plus an additional legislative proposal, the effects of which will be of importance to certain severely disabled Vietnam veterans and survivors of some who are deceased.

Subsequent to discussing the legislative initiatives, we shall express our views on the current state of the research on the issue of Agent Orange exposure, and related subjects.

S. 1692 - Would amend title 38, United States Code, by providing that, in the case of any veteran who served in the Republic of Vietnam during the Vietnam War, the disease of non-Hodgkin's lymphoma shall be considered to have been incurred in or aggravated by that service, notwithstanding that there is no record of evidence of such disease during the period of service.

This measure is self-limiting, in that it provides that it shall not be applicable in the case of any claim received by the Veterans Administration after September 30, 1991.

The presumption of service connection would not apply in the case of the disability or death of a veteran as a result of non-Hodgkin's lymphoma if 1) there is affirmative evidence that such disease was not incurred by the veteran during the performance of service in the Republic of Vietnam during that era; 2) there is affirmative evidence to establish that an intercurrent injury or disease was suffered by the veteran between the date of the veteran's latest departure from Vietnam while on active duty and the onset of the disease; or, 3) the Administrator determines, based on evidence in the veteran's service records and other records of the Department of Defense, that the veteran was not exposed to herbicides while on active duty in Vietnam.

The American Legion supports the establishment of the presumption of service connection for non-Hodgkin's lymphoma. However, we question the inclusion of the sunset date of September 30, 1991, as no explanation for that has been offered.

S. 1787 - calls for an amendment to title 38, to prescribe certain presumptions in the case of veterans who performed active service in Vietnam during the Vietnam War.

The bill would amend section 312 of title 38, which sets forth presumptions of service connection, by adding a new subsection establishing, for the purpose of disability compensation, that in the case of any veteran who served on active duty in the Republic of Vietnam during the Vietnam War, the following diseases shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during service: 1) Non-Hodgkin's lymphoma; 2) Lung cancer becoming manifest within 25 years after the last date on which the veteran served in Vietnam; 3) A disease that is determined to be reasonably associated with damage to or suppression of the human immune system resulting from exposure to herbicides used in Vietnam.

Determinations relating to the diseases associated with the immunosuppressive effects of the herbicides would be made by an appropriate nonprofit private scientific organization, with which the Administrator shall enter into an agreement. Under the provisions of this measure the nonprofit private scientific organization, whether it be the National Academy of Sciences or another appropriate organization, would be required to do several things. It would be required to conduct a survey of all completed and ongoing scientific studies of the effects that dioxin and other toxic herbicides used in support of United States and allied military operations in the Republic of Vietnam during that era have on humans or other animals that have been exposed to the herbicides.

The organization would determine in the case of each such herbicide, on the basis of the studies, what (if any) diseases are reasonably associated with damage to or suppression of the human immune system resulting from exposure to the herbicide. Within a year of enactment, NAS or other appropriate organization would submit a report to the Veterans Affairs Committees listing the disabilities associated with immunosuppression resulting from exposure to dioxin or other toxic herbicides.

The Administrator would then be required to add those disabilities to the list of compensable disabilities, since their service connection would already be presumed, based upon provision of this measure.

S. 1787 would further direct the Administrator to compile and analyze on a continuing basis, all clinical data obtained by the Veterans Administration in connection with the Agent Orange examinations, and treatment furnished by VA to Vietnam veterans under authority of PL 97-72, based upon exposure to dioxin or other toxic substances. The Veterans Administration would be required to submit a report on the disabilities treated and the incidence of the disabilities to the Committees on Veterans Affairs within one year, and thereafter on a semiannual basis.

Mr. Chairman, The American Legion, as mentioned previously, fully supports the establishment of a presumption of service connection for non-Hodgkin's lymphoma based upon exposure to Agent Orange. We feel that there is adequate scientific evidence on which to base such a presumption.

Mr. Chairman, the results of a study entitled "Agricultural Herbicide Use and Risk of Lymphoma and Soft-Tissue Sarcoma", conducted by the National Cancer Institute and the University of Kansas, were published in the Journal of the American Medical Association in September 1986. The population-based case-control study reported that a significant number of farmers who were exposed to herbicides containing phenoxyacetic acid, specifically 2,4-dichlorophenoxyacetic acid (2,4-D).

The Kansas study conclusions said that farmers using the herbicides for 20 days per year or more had a six-fold higher rate of the lymphoma than non-farmers. In some cases the rate was as much as eight-fold. The findings showed that human exposure to herbicides containing phenoxyacetic acid - a component of Agent Orange - did not increase the risk of soft-tissue sarcomas and Hodgkin's Disease, but did increase the risk of non-Hodgkin's lymphoma. It should be noted that the herbicides used by most of the farmers in the study were reported not to contain 2,4,5-T, the other important phenoxyherbicide and the source of 2,4,7,8 - TCDD (dioxin) in Agent Orange.

The Kansas study confirms the results of a Swedish case-control study by Hardell et al that suggests an association between herbicides and non-Hodgkin's lymphoma.

With respect to the presumption of service connection for lung cancer, while we do not oppose it, we do feel that there is a need for some clarification with respect to causation, and the types of cancer indicated.

The America Legion also supports the section of S. 1787 that would mandate the establishment of an agreement between the Veterans Administration and a scientific organization to conduct a study of the literature and studies on the effects of dioxin to determine what diseases are reasonably associated with damage to or suppression of the human immune system resulting from herbicide exposure.

Although there are those who will undoubtedly argue that the Kansas study is not sufficient evidence on which to base a presumption of service connection for NHL, The American Legion submits that it must be viewed as adequate because of the lack of conclusive evidence to the contrary, and based upon the manner in which the issue of Agent Orange exposure has been mishandled by the Federal Government. This will be addressed in greater detail in a moment.

S. 1805 - Although this measure is not scheduled for consideration during today's hearing, we feel that it is important legislation which needs to be deliberated by the Congress at least by the time the Supreme Court decides the case that is holding up the payments from the Agent Orange product liability litigation.

This bill would exclude payments made to veterans or their survivors under the Agent Orange liability settlement fund from being counted as income when determining eligibility for or entitlement to a veteran's or survivor's pension, or a veteran's medical care under Category A of the means test provisions.

In May 1984, the Agent Orange case was settled for $180 million. The court adopted a distribution plan intended to provide assistance to those members of the class who are in the most difficult circumstances. Under the distribution plan, approximately $150 million of the settlement fund will be allocated to the Agent Orange Veteran Payment Program. The payment program will provide cash awards to certain totally disabled Vietnam veterans and the surviving spouses and children of certain deceased Vietnam veterans.

Veterans who can show exposure to Agent Orange while serving in or near Vietnam from 1961 to 1972 and who are currently suffering from a long-term total disability based upon Social Security rating criteria, which occurred prior to the veteran's 60th birthday and is not caused by trauma, accident, or self-infliction, could receive payments under the settlement.

Spouses or dependent children of deceased veterans who qualify under the above criteria should also receive payments.

Tentatively, veterans could receive a maximum of $12,800 and survivors could receive up to $3,400 under the settlement plan. Veterans or survivors who receive nonservice-connected disability or death pensions would have their pensions reduced on a dollar-for-dollar basis for any payment received under the Agent Orange settlement, and in some cases the entire pension could be discontinued because of this modest income.

S. 1805, as mentioned previously, would exclude the payments from being counted as income for pension purposes, or as income with respect to the means test for Veterans Administration medical care. The American Legion fully supports the intent of this proposal. However, we would recommend that the exclusion of income be extended beyond Veterans Administration programs, to include any need-based government assistance program.

Mr. Chairman, although we brought it to the Committee's attention once before, it bears repeating at this time, that The American Legion is deeply troubled by the Centers for Disease Control's conclusion that the agency cannot find enough Vietnam veterans who were exposed to Agent Orange to do a scientifically valid study of the herbicide's effects on humans.

We are troubled by CDC's conclusion for several reasons. But first, may we digress a moment and mention that about twenty months ago, The American Legion expressed concern about the fact that the Agent Orange study mandated by PL 96-151, which had been taken over by CDC, had become mired in major administrative and methodological problems that had forced the study to a standstill. We stated then that in mid-1985 the Agent Orange study began to deteriorate. There were several changes in the position of study director. CDC began working outside of the originally approved study protocol, which resulted in the Office of Technology Assessment recommending that the study be delayed until a revised protocol was developed and approved, to include an acceptable exposure assessment method. As was stated to this Committee on September 24, 1986, The American Legion was seriously concerned about the status of the CDC Agent Orange study.

It was no suprise to us then, that after conducting a pilot study of its own design, CDC has concluded that the study cannot be done. We also voiced concern about the composition of the study population almost two years ago. Among the veterans eliminated from consideration were those who served more than one tour in Vietnam, those who served in a particular unit for less than 180 days, those who were above the rank of E-5, those who transferred from one unit to another during their tour, and any veteran who served any number of days before or after the proposed study window (January 1967-December 1968). These constraints may appear to be trivial to some, but they eliminated thousands of veterans, many of whom were no doubt heavily exposed to Agent Orange. In fact, it is reported that 83 percent of the original study subjects were disqualified based on criteria set forth by CDC.

The United States sprayed more than 12 million gallons of Agent Orange over a country that is smaller than the State of New Jersey. Therefore, we feel it absurd for CDC officials to state that they cannot find enough people to study. It is unfortunate that CDC was permitted to develop a study that was destined to fail.

The American Legion is mandated to take any and all steps necessary to ensure that the Congressional mandate set forth for an Agent Orange study in PL 96-151 is followed, and that the study is completed as expeditiously as possible.

To that end, we urge the assistance of this Committee in ensuring that the Federal Government fulfills its responsibility to Vietnam veterans and their families by providing answers to the agonizing questions relating to the health effects of exposure to Agent Orange. We are quite aware of and thankful for the interest and concern that has heretofore been expressed by this Committee as problems have developed in this study, and we trust that it will continue.

Mr. Chairman, the responsibility for determining the diseases that may be presumed to be service-connected as a result of Agent Orange exposure was in effect transferred from the Congress to the Veterans Administration with the enactment of PL 98-542, the Veterans Dioxin and Radiation Exposure Compensation Standards Act, enacted on October 24, 1984.

One of the provisions of the Act provided that the Administrator, pursuant to a freestanding provision of law rather than an amendment to title 38, would pay a monthly disability benefit only to certain veterans who served in the Republic of Vietnam, and who incurred either chloracne or porphyria cutanea tarda which became manifest within one year after the date of the veteran's last departure from Vietnam while on active military duty. In the event that a veteran died from either such disease, the Administrator was to pay a monthly death benefit to the veteran's survivors. Benefits were not to be paid in cases where there was affirmative evidence that the disease was not incurred by the veteran during service in Vietnam; where there was affirmative evidence to establish that an intercurrent injury or disease which is a recognized cause of the disease was suffered by the veteran between the date of the veteran's most recent departure from the Republic of Vietnam and the onset of the disease; or if it is determined that evidence in the veteran's service record and other records shows that the veteran was not exposed to dioxin while serving in the Republic of Vietnam during the Vietnam War.

The effective date of benefits established by that Act was October 1, 1984. No benefit was to be paid for a period before that date, and no benefit was to be paid for any period after September 30, 1986.

Mr. Chairman, to the best of our knowledge, no benefit was paid, period.

PL 98-542 also directed VA to promulgate regulations relating to the adjudication of individual claims, to include guidelines, standards and criteria where appropriate. Additionally, the Administrator was to make determinations, based on "sound scientific and medical evidence", after receiving the advice of the Veterans Advisory Committee on Environmental Hazards that was established by the law, as to whether service connection would be granted for chloracne, porphyria cutanea tarda, and soft-tissue sarcoma in the case of veterans exposed to Agent Orange.

In the final regulations the Veterans Administration denied the presumption of service connection for porphyria cutanea tarda and soft-tissue sarcomas, and provided only a three-month presumptive period for the service connection of chloracne.

As of this time, almost four years subsequent to the enactment of this law, no additional conditions have been determined by the Administrator to be presumed to be service-connected based on exposure to Agent Orange.

Given the emotional climate in which this entire matter has been and is now being considered, we believe it would be well for the Federal Government to lean in the direction of liberality while the remaining scientific questions are resolved.

Mr. Chairman, The American Legion is appreciative that you have scheduled hearings on this issue which is of such extreme importance to Vietnam veterans and their families. It is frustrating for those of us who represent Vietnam veterans to try to explain to them, and their families, why little or nothing is being done to determine the long-term health effects of exposure to Agent Orange, or to compensate those who are suffering chronic disabilities which they feel are caused by such exposure.

The American Legion holds fast to the position that it is the responsibility of the United States Government to use every resource available to determine the consequences of exposure to Agent Orange on those veterans who served in the Armed Forces in Vietnam, and then to adequately compensate those who are suffering from diseases and disabilities as a result of that exposure.

Thus far, as far as we are concerned, the government has fallen far short of its responsibility.

Mr. Chairman, that concludes our statement.

STATEMENT OF
DAVID W. GORMAN
ASSISTANT NATIONAL LEGISLATIVE DIRECTOR
FOR MEDICAL AFFAIRS
DISABLED AMERICAN VETERANS
BEFORE THE
SENATE COMMITTEE OF VETERANS AFFAIRS
MAY 12, 1988

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

On behalf of the more than 1.1 million members of the Disabled American Veterans and its Ladies' Auxiliary, may I say how very much we appreciate the opportunity to appear here today to comment on legislation -- S.1692 and S.1787 -- dealing with the subject of Agent Orange. Additionally, Mr. Chairman, you have the sincere appreciation of the DAV for the timely conduct of these hearings regarding this most important issue.

As you know, Mr. Chairman, Agent Orange was the most commonly used of several powerful defoliant chemicals sprayed extensively in Southeast Asia during the Vietnam war to deprive the enemy of ground cover and destroy the food supply. The chemical derived its name from the orange stripes that marked the 55 gallon drums in which it was shipped to the war zone.

Military Use of Herbicides and Other Chemicals in South Vietnam

The Department of Defense field tested herbicides in Vietnam as early as 1961 and carried out military herbicide operations from 1962 to 1971. The herbicides were used primarily for (1) defoliating trees and plants to improve observation and (2) destroying food crops of hostile forces. The herbicides used were:

* Herbicide Orange, a 50:50 mixture of 2,4-D and 2,4,5-T, was the most widely used herbicide in Vietnam. The component

2,4,5-T contains a contaminant, TCDD (2,3,7,8 -- tetrachlorodibenzopara-dioxin) which is one of the most toxic chemicals known.

- Herbicide Purple, (a similar mixture of 2,4-D and 2,4,5-T that contained a different form of 2,4,5-T -- that was later replaced by herbicide orange in 1964).

- Herbicide White, a mixture of 2,4-D and Picloram.

- Herbicide Blue, cacodylic acid.

According to military estimates, about 17.7 million gallons of herbicides were sprayed during the 1962 to 1971 time frame. From 1965 to 1971, the military sprayed 10.65 million gallons of Agent Orange, 5.63 million gallons of Agent White and 1.14 million gallons of Agent Blue. The National Academy of Sciences (NAS) estimates that of the 3.6 million acres sprayed, 66% was sprayed once, 22% was sprayed twice, 8% was sprayed three times and 4% of the land area was sprayed four or more times.

Agent Orange was sprayed undiluted in Vietnam at the rate of about three gallons -- containing 12 pounds of 2,4-D and 13.8 pounds of 2,4,5-T -- per acre. Civilian applications of this herbicide's components are usually diluted in oil or water. According to industry officials, the civilian application rate of 2,4,5-T varies from one to four pounds per acre. The military contends that the heavier application used in Vietnam was needed to assure success of the various spraying operations. Military officials also contend that due to the dense jungle canopy, the amount of herbicide penetrating the forest floor would have been similar to those normally applied to brush infested land in the continental United States.

In October 1969, the use of Agent Orange was restricted to areas remote from population. This action was prompted by a

National Institutes of Health Report that 2,4,5-T could cause malformations and stillbirths in mice. Research later attributed similar problems to the contaminant TCDD, which is produced during the manufacture of Agent Orange. In April 1970, all use of Agent Orange in Vietnam was suspended. About the same time the Department of Agriculture restricted certain domestic uses of the herbicide because of its possible health hazards.

In 1971, the Air Force was directed to dispose of all remaining stock of Agent Orange. The Air Force has reported that their existing stock of Agent Orange was disposed of at sea by high temperature incineration during 1977.

Previous Legislative Actions

Public Law 96-151. "The Veterans' Health Programs Extension and Improvement Act of 1979," enacted December 20, 1979, mandated the VA to conduct a epidemiological study of the possible adverse health effects of exposure of persons who served in the military in Vietnam to the category of chemicals known as "dioxins" produced during the manufacture of Agent Orange. After approximately two years of virtually no action by the VA, the responsibility for the conduct of the study was transferred to the Centers for Disease Control (CDC) on January 14, 1983. The VA also received the mandate to conduct a comprehensive review and analysis ot scientific literature relating to possible adverse health effects from exposure to Agent Orange.

Public Law 97-72. The "Veterans' Health Care, Training and Small Business Loan Act of 1981," enacted November 3, 1981, authorized the VA to provide medical treatment to eligible Vietnam veterans who felt their disability may have been caused by exposure to dioxin or to a toxic substance used in Vietnam. Authority to provide these health care services is scheduled to expire on September 30, 1989.

Public Law 98-542. The "Veterans' Dioxin and Radiation Exposure Compensation Standards Act," enacted October 24, 1984, required the VA to specify standards for deciding compensation claims based upon exposure to Agent Orange or to radiation.

This act also required the VA to establish a Veterans' Advisory Committee on Environmental Hazards. The purpose of the committee is to advise the Administrator on VA regulations, completed and ongoing research and other administrative and legislative initiatives.

Public Law 99-272. The "Consolidated Omnibus Budget Reconciliation Act of 1985," enacted April 7, 1986, mandated the VA to provide for the conduct of an epidemiological study of any long term adverse health effects experienced by women who served in the Armed Forces in Vietnam. The study is to examine health effects, particularly gender-specific health effects, which may have resulted from traumatic experiences during such service, or from exposure to Agent Orange or other herbicides. It is anticipated that a contract for the conduct of this study will be awarded during Fiscal Year 1988.

Combined Federal Activities

In late 1979, the White House established an Interagency Work Group to bring together knowledgeable government scientists to oversee the research, develop areas where scientific study is needed, and report the results as soon as they became available to both the Congress and the general public.

On August 21, 1981, the Agent Orange Working Group (AOWG) was established as part of the Cabinet Council on Human Resources. This action elevated and enlarged the scope of the Interagency Work Group.

On April 11, 1985, the eight Cabinet Councils, including Human Resources were combined into two, the Council on Economic Policy Council and the Council on Domestic Policy to which the AOWG now reports.

The Agent Orange Working Group is under the leadership of the Department of Health and Human Services and includes scientific, legal and policy representatives from that Department, as well as the Departments of Agriculture, Defense, Labor and State, and the Veterans Administration, the Environmental Protection Agency, the White House Office of Science and Technology Policy, Office of Management and Budget and the Office of Technology Assessment.

Mr. Chairman, currently, there are some 70 ongoing research projects and 80 completed research projects dealing with dioxin related research efforts.

Federal Agencies conducting the bulk of current research include the Centers for Disease Control/Center for Environmental Health; Centers for Disease Control/National Institute for Occupational Safety and Health; Department of Defense; National Cancer Institute; National Institute of Environmental Health Services; Environmental Protection Agency; and the Veterans Administration.

Mr. Chairman, in excess of $91 million has been spent thus far on dioxin related research. An additional $122 million has been spent on the 70 ongoing projects to date and a projection of $188 million is estimated to be necessary over the next two decades to complete the current ongoing projects.

Of the 70 ongoing projects, 11 deal directly with Agent Orange issues and the remainder deal with dioxin related issues. However, the 11 Agent Orange projects expend about 78% of the current funding for ongoing projects and are projected to utilize over 93% of the future funding required to complete the total number of ongoing projects.

As you are aware, Mr. Chairman, the Centers for Disease Control (CDC) which has been mandated to conduct the most comprehensive study to date on the health effects of Agent Orange -- the "Agent Orange Study" -- terminated, in September 1987, their contracts under which they had planned to conduct the study. That action effectively cancelled the CDC Agent Orange Study mandated by Public Law 96-151.

CDC's action was predicated upon their determination that it was not possible to identify a large enough number of exposed veterans -- based on military records -- upon which to base a large scale study.

Frankly, Mr. Chairman, we view CDC's decision to totally abort their study incredulous and simply an acknowledgement that their preferred method of conducting such research was not felt feasible.

In our view, efforts to conduct this vital study had preceded at no better than a "snail's pace," since the enactment of Public Law 96-151 in 1979. There is little need here to engage in dialogue of the historical events leading up to the recent announcement cancelling the study. Suffice it to say the best interests of the government and, more importantly, Vietnam veterans have not as yet been served. We are aware of additional efforts being undertaken by other sources that instill some optimism that such a study can in fact be accomplished and done so in a scientifically sound and acceptable manner. (This issue will be addressed later in our testimony.)

Mr. Chairman, it has been over 20 years since the initial spraying of Agent Orange occurred in Vietnam. Since that time untold thousands of veterans and their families have been fearful, confused, frustrated, uninformed and extremely patient while waiting for answers to be found or for action to occur.

They still wait patiently. They wait for their government, their nation, to acknowledge various maladies as possibly being related or unrelated results of their military service and exposure; or they wait for signs that progress is being made in that direction. Further, they wait for some degree of assurance that the government is really doing something to address their concerns in an honest, forthright and meaningful fashion. Many feel this is not occurring.

Mr. Chairman, there appears to be a general consensus that the scientific and medical communities will not, in the foreseeable future, be in a firm position to provide answers to the many questions surrounding the issue of what, if any, adverse health effects result from exposure to Agent Orange.

Clearly, to expect veterans to wait until a large scale epidemiological study and/or long term research is completed is not a realistic response. We view the current process to be slow, tedious and totally inadequate. In our view, the time for affirmative, reasonable and meaningful action has long since arrived.

S. 1692

At the outset, Mr. Chairman, the DAV wishes to acknowledge and applaud Senator Murkowski for his efforts in constructing and introducing S. 1692.

Section 2(a) of this measure would; (1) amend Section 312, Title 38, United States Code (USC) to provide presumptive service-connection to veterans who served in Vietnam and subsequently developed non-Hodgkins' Lymphoma as a result of presumed exposure to Agent Orange; and (2) establish a sunset date -- September 30, 1991 -- after which the presumption will not apply to any claims received by the VA.

Section 2(b) would, via appropriate amendment to Section 313, Title 38, USC, provide for the presumption of service-connection to be rebutted in the presence of affirmative evidence.

Mr. Chairman, the DAV strongly and whole-heartedly supports this measure as it would satisfy a mandate of the delegates to our most recent National Convention (DAV Resolution No. 116 copy attached).

In our view, a sufficient body of scientific and medical evidence exists to adequately support this measure. As we have indicated previously none of the research is yet precise -- and it may never be -- in establishing a relationship between exposure and subsequent developing disease.

However, the weight of the research conducted relating to non-Hodgkins' Lymphoma is sufficient, in our opinion, to tip the balance when considering this particular disability. The most notable research efforts to date include:

* A study of Kansas farm workers which showed a 6 fold increase of non-Hodgkins' Lymphoma in exposed farmers; and

* A VA study "Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War," which showed Marines who served in Vietnam had a 110% higher death rate than expected as a consequence of non-Hodgkins' Lymphoma.

Other significant studies have tended to indicate the relationship between exposure to dioxin and the development of non-Hodgkins' Lymphoma.

Therefore, as previously stated, the DAV is pleased to lend its support to S. 1692.

S. 1787

Mr. Chairman, we would like to take this opportunity to acknowledge and thank Senator Daschel for his continued interest and support for Vietnam veterans as evidenced by the introduction of S. 1787.

Mr. Chairman, the DAV supports that portion of Section 3(a) that would extend service-connection, on a presumptive basis, for non-Hodgkins' Lymphoma arising in veterans who were exposed to Agent Orange during service in Vietnam.

However, we are unable, at this time, to support the granting of service-connection on a presumptive basis for lung cancer or, as broadly stated, a disease that is associated with damage to or suppression of the human immune system. We are simply not now privy to sufficient documentation to support such a provision.

Section 3(b) proposes to amend Section 313, Title 38, USC precluding the applicability of Subsection (a) for the diseases subject to presumption under Section 3(a) of the bill.

If enacted, Section 3(b), would, in our view, run counter to the tenets of the VA's disability compensation program. As vigorously as the DAV supports and advocates the principles of granting service-connected compensation benefits for the residuals of disease or injury occurring as a result of military service, we oppose any effort that would, in our view, prove detrimental to the integrity and very purpose of the compensation program.

Section 313, Title 38, USC in allowing for presumptions of service-connection to be rebutted, encompasses the concept of utilizing sound medical principles and the entire evidentiary record in the adjudication of compensation claims. In our opinion, this represents sound and accepted adjudication principles. Therefore, we are unable to support, as contemplated by Section 3(b), this modification relating to rebuttable presumptions.

Likewise, the proposed changes concerning the effective dates for payments of benefits, as proposed in Section 3(c), is a radical departure from established principles that are, in our view, equitably stated and applied.

Mr. Chairman, with respect to Section 4 of the bill, we have no objection to implementing a procedure that would require the VA to seek a mechanism attempting to identify and determine -- based on available scientific literature -- specific disabilities that are reasonably associated with exposure to Agent Orange.

We would offer a cautionary note, however, that the organization charged with this responsibility not proceed in a passive manner or be duplicative of similar ongoing studies and efforts. Of course, following a review of any report findings made as a result of such a survey, we will be pleased to again revisit the issue of presumptive service-connection for certain specific disabilities.

While we feel it beneficial to enlist the aid of a nonprofit private scientific organization to develop what, if any, specific disabilities may be reasonably associated with exposure, we do not feel it prudent to require the Administrator to accept, carte blanche, such a list and implement regulations to grant service-connection for such disabilities. This would be tantamount to requiring the Social Security Administration to adopt the VA Schedule for Rating Disabilities in all of their determinations pertaining to the award or denial of Disability Insurance Benefits. We believe discretion should be conveyed to the Administrator, with appropriate Congressional input, to determine what disabilities may be included in such regulations.

Mr. Chairman, Section 5 of the bill would require the Administrator to compile and analyze, on a continuing basis, all clinical data obtained by the VA in conjunction with examinations and treatment furnished to veterans, after November 3, 1981, who received medical care from the VA based on their service in Vietnam and claimed exposure to Agent Orange.

Additionally, the Administrator would be required to submit to the Veterans Affairs Committees a report containing:

1. The clinical information compiled;
2. The Administrator's analysis of such information;
3. A discussion of the disabilities identified or treated by the VA in the case of veterans receiving such treatment;
4. The Administrator's explanation for the incidence of such disabilities; and
5. Other explanations for the incidence of such disabilities as considered reasonable by the Administrator.

Mr. Chairman, we agree with the intent of Section 5. It is our belief that an exercise of compiling and analyzing the examination and treatment results of certain veterans may indeed prove beneficial and assist in the search for solutions to the Agent Orange issue.

Recommendations

Mr. Chairman, in addition to the various provisions of S. 1692 and S. 1787, which have been addressed, we believe the Committee should consider three additional concepts that will, in our view, constitute a reasonable and meaningful approach in attempting to address the needs of Vietnam veterans.

1. The creation of an "archives" -- the process of maintaining frozen blood samples -- of Vietnam veterans who believe they were exposed to Agent Orange. Samples would be available over the long term for medical analysis as research endeavors may dictate a need.

2. Direct the VA to dedicate sufficient funds for investigator initiated "pilot research studies" of specific components dealing with the Agent Orange issue. (An example of such a "pilot study" may be to develop -- as an alternative to the CDC protocol for the Agent Orange Study -- a feasible and scientifically accepted method of identifying a sufficiently large number of exposed veterans in order to proceed with a large scale study to investigate any adverse health effects of exposure to Agent Orange.)

It seems reasonable that if efforts were undertaken to identify and reach consensual scientific conclusions on individual components of the issue than, a subsequent large scale study may be successfully conducted. This approach differs from the previous theory of proceeding "full speed ahead" to find the many answers surrounding this controversy. In essence, these studies will represent small individual pieces of the puzzle that, when joined together, may represent a clearly visible plan on which to proceed.

3. Direct the Administrator to engage in an active, continual program of outreach services to Vietnam veterans.

Such action would ensure that Vietnam veterans are being provided with current, meaningful information and publications regarding ongoing efforts to address and resolve the many complex issues regarding the health effects of Agent Orange. In the past the VA had printed and furnished, to veterans on the Agent Orange registry, literature and updates regarding the Agent Orange issue. To our knowledge, no such literature has been distributed since March 1986. Obviously, countless thousands of Vietnam veterans and their families are anxious to learn of current efforts being undertaken regarding Agent Orange. It is our opinion that the VA should be the lead agency in disseminating such information. Therefore, we feel that the VA should be directed to provide such outreach and information dissemination services and to do so on a regular basis, i.e. at least twice a year.

Mr. Chairman, this concludes our testimony. Again, I want to thank you for allowing us this opportunity to present the views of the DAV regarding this most complex, frustrating and important issue.

PVA
PARALYZED VETERANS
OF AMERICA
Chartered by the Congress
of the United States

STATEMENT OF

JOHN C. BOLLINGER, ASSOCIATE LEGISLATIVE DIRECTOR

PARALYZED VETERANS OF AMERICA

BEFORE THE

SENATE COMMITTEE ON VETERANS' AFFAIRS

CONCERNING

MATTERS RELATING TO AGENT ORANGE

S.1692, "THE AGENT ORANGE DISABILITY BENEFITS ACT OF 1987"

AND

S.1787, "THE VETERANS' AGENT ORANGE DISABILITY ACT OF 1987"

MAY 12, 1988

Mr. Chairman and Members of the Committee, it is a privilege for me to be here today to present the views of Paralyzed Veterans of America (PVA) on the status of studies reviewing the potential health effects within the Vietnam veteran population following exposure to herbicides.

PVA also appreciates the opportunity to comment on specific legislation S. 1692, "The Agent Orange Disability Benefits Act of 1987," introduced by Senator Frank H. Murkowski, and S. 1787, "The Veterans' Agent Orange Disability Act of 1987," introduced by Senators Thomas A. Daschle and John F. Kerry. Both bills would provide compensation for service-connected disability for Vietnam Veterans suffering certain diseases or illnesses presumed to be associated with exposure to Agent Orange or similar defoliants sprayed in Southeast Asia during the Vietnam War.

Senator Murkowski's bill, S. 1692, would provide a rebuttable presumption for disability compensation for non-Hodgkins lymphoma (NHL). Senator Daschle's and Senator Kerry's bill, S. 1787, would provide a non-rebuttable presumption of service-connection for Vietnam Veterans who have NHL, lung cancer, or certain immunosuppressant disabilities still to be determined. The legislation would also require the VA to collect and analyze additional health data on all Vietnam veterans potentially exposed to Agent Orange.

Mr. Chairman, the search for clues to discover any potentially adverse health effects of exposure to Agent Orange has been long and convoluted. Millions of dollars have been spent in what can only be described as one of the most extraordinary scientific investigatory efforts involving epidemiology in history. Since the late 1970's, when this effort first began, the investigation has travelled a rocky road. The search faced initial bureaucratic inertia. Subsequently, it has proceeded in an all-out effort to, first, develop the science, and then determine through that science if Vietnam Veterans are, or could in the future be, at risk of suffering life threatening diseases as a result of exposure to minute quantities of a toxic agent while serving in Southeast Asia some twenty-five years ago.

At times, the science has not been perfect. Many times the full commitment to pursue that science has not been complete. But we are still much farther down that road than we were ten years ago.

Vietnam veterans and their families, now, have far more answers as to their overall health status than they did before. Still, as this investigation is pursued, we might never find the proper combination of clues which could establish a concrete link between exposure to Agent Orange and certain diseases. That should not stop us from supporting any effort to do so. But in the meantime, we should be cautioned not to endorse or provide compensation for such disabilities unless we can be certain there is a realistic connection between exposure to Agent Orange, and its containment dioxin, and that disability.

PVA would like to commend Senator Murkowski, Senator Daschle and Senator Kerry for their deep concern in introducing the legislation before us today. Over the years we have shared their frustration and this Committee's frustration in dealing with the Agent Orange question. Both bills keep the attention of the Congress on this important concern which we believe to be proper. However, PVA does not believe that a connection can currently be found and firmly established between exposure to Agent Orange in Vietnam with disabilities that can be extrapolated to the entire Vietnam veteran population based on the scientific evidence we have reviewed to date.

The presumptions for disability compensation called for in both S. 1692 and S. 1787 - non-Hodgkins lymphoma and lung cancer are drawn from only the partial results of the VA's study entitled "Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War," released in 1987. The study reviewed patterns of mortality among veterans of the Army and Marine Corps who served in Vietnam, and Vietnam era Army and Marine Corp veterans who served in areas other than Southeast Asia.

Senator Murkowski's legislation would give the VA Administrator the authority to investigate and rebut the veteran's claim based on medical and service record evidence showing that the NHL had causes not related to the veteran's service in Vietnam or potential exposure to herbicides. Section 3(b) of S. 1787 would amend Section 313 of title 38 U.S.C. by making the veteran's claim nonrebuttable by the VA. PVA believes such an exclusion would be a major departure from existing VA claims adjudication procedures which allow the VA to review the entire evidentiary record to determine if a case has a sound basis.

The presumption for disability compensation for certain immunosuppressant diseases contained in S. 1787 was not based on attributable findings of mortality appearing in the recent VA study of veterans, but is drawn from other studies including studies of non-Vietnam veterans which have suggested a link between persistent exposure to dioxin and these diseases. The bill calls on the National Academy of Sciences, or a similar body, to review scientific literature to propose to the Congress what disabilities should be included on this list. The claim to support higher evidence of NHL is cited by a National Cancer Institute study which documented a higher incidence of that disease among Kansas farm workers who regularly, over a period of years, used the herbicide 2,4-D, a component of Agent Orange - again, not Vietnam veterans.

The VA's recent study reviewed the records of former Army and Marine Corps personnel to determine the cause of death of 51,421 veterans. Death certificates were used in 96.9 percent of all cases. Forty-nine percent of the group served in Vietnam. Fifty-one percent were Vietnam Era veterans with no "in country" service. The study excluded veterans who did not serve between July 4, 1965, and March 1, 1973; Navy, Air Force and Coast Guard personnel; personnel killed in action, missing in action; those who died of war related injuries; and all women veterans.

The major findings of the study state:

- As a group there appears to be no remarkable difference in the major causes of death between the men who served in Vietnam and veterans who did not serve in Vietnam, with few exceptions.
- Motor vehicle accidents account for 35 percent of deaths.
- Other non-motor vehicle accidents were primarily among Army veterans with 51 percent aircraft accidents.
- Accidental poisonings were elevated among both Army and Marine Corps veterans. In reviewing 100 of these deaths, it was found that 98 percent were due to narcotic overdose, mostly heroin.
- When all malignancies were grouped, Army and Marine Corps Vietnam veterans did not exhibit an excess of cancer when compared to their counterparts who did not serve in Vietnam.
- Although suicide is generally under-reported on death certificates, there appears to be no statistically significant excess of suicide

in the Vietnam veteran population vs. their Vietnam Era veteran counterparts.

- Although some studies have suggested that individuals exposed to dioxin could be at increased risk of soft-tissue sarcoma, no excess was seen among Vietnam veterans in this study.

- Marine Corps veterans were seen to have a statistically significant excess of non-Hodgkin's lymphoma when compared to Marines who did not serve in Vietnam. However, this pattern did not appear among Army "in-country" Vietnam veterans (indicating the potential existence of other environmental influences).

- Lung cancer deaths were elevated significantly among Vietnam veteran Marines relative to Marines with no Vietnam experience. But, the Army Vietnam veterans did not demonstrate this higher incidence of death due to lung disease. The study, as well, did not assess if those Marine Corp Vietnam veterans who died of lung cancer had histories of tobacco use. Further review of this correlation has been suggested.

From an epidemiological standpoint, taking both Army and Marine Corps Vietnam veterans as a group and comparing them with equivalent veterans who did not serve in Vietnam, there appears to be no major difference in the mortality experience of either veteran cohort. Only when the main group is broken into subgroups do certain statistical anomalies appear - namely, the NHL and lung cancer deaths among Marine Corps Vietnam veterans only. Both the Office of

Technology Assessment (OTA) and other noted scientists who were asked to review this study have questioned the reliability of these findings and suggested that further analysis necessary before these conclusions should be judged valid.

PVA believes that in breaking the main study group down, the statistical credibility of the entire study is greatly weakened. Attempting to transfer statistical fact from a subgroup (Marine Corps Vietnam Veterans) to imply general liability for incidence of a disease within the study group as a whole does not make a good case in our opinion. Yet, both bills before us today would do just that. They would provide a presumption for service-connection disability for NHL and lung cancer for the entire Vietnam veteran population based on the findings tabulated only for the Marine Corps Vietnam veterans. This would be done regardless of the fact that the study did not review the mortality experience of Air Force, Navy and other in-country Armed Forces personnel. Or, that the Army Vietnam veterans who served in areas where they could have had potentially higher levels of exposure to Agent Orange exhibited none of the same statistical significant elevations in causes of mortality.

Perhaps, this is the most consistently troubling aspect of attempting to solve the Agent Orange dilemma. Both bills would utilize the VA's definition to quantify veterans exposed to Agent Orange as: "Any veteran who performed active military, naval or air service in the Republic of Vietnam during the Vietnam Era" is considered exposed.

This definition admits the current failure of science or historical record to identify exactly who, of the three million men and women who served in Vietnam, were exposed to Agent Orange; when they were exposed; and how much dioxin they were exposed to. The Centers for Disease Control attempted to develop an "exposure index" for its authorized Agent Orange study and admitted that it just can't be done in such a way as to produce an unchallengeable scientific result.

So, on the one hand, we don't really know who was exposed to Agent Orange. Newly developed scientific techniques which can assay dioxin levels by parts - per - billion in blood samples taken from Vietnam veterans, today, could help to trace clues to exposure twenty-five years ago. But who is not to say that those trace elements in a veteran's blood were not absorbed or ingested by exposure to this chemical compound which has been in commercial use and environmentally pervasive in this country, not just Vietnam, for decades.

On the other hand, we have no clear idea of what exposure to dioxin can do to you. We know it is highly toxic. But in what amounts and to what degree and over what period of time and exposure level does it manifest that toxicity in the human body.

In the case of atomic veterans exposed to ionizing radiation, we can identify who was present at a nuclear test. Granted, record keeping on exposure levels was primitive. Monitoring from radiation badges worn by service personnel was inconsistent in recording exposure for all participants. But, from what we know about nuclear physics, if a sailor was within close proximity to a hydrogen bomb detonation, on a particular day, and stayed in that area for a certain period of time following the blast, the chances are that sailor was exposed to radiation. The VA can identify who he is.

Nuclear science, as well, is very clear that such exposure has specific latent effects which can cause identifiable disabilities years later. For this reason, PVA believes that the Congress has acted reasonably and responsibly in authorizing compensation for certain disabilities experienced by atomic veterans. However, we have no similar definitive scientific information on either exposure or cause and effect with regard to Agent Orange and Vietnam veterans.

Vietnam veterans, in a combat situation, over a period of months in a tropical environment, were exposed to a multitude of potentially harmful experiences and agents which can carry with them long-term deleterious effects. Severe stress reactions and disorders brought on by combat experiences are well-documented to manifest long-term psychological as well as collateral physical debilitation. Likewise, exposure to a tropical environment brings contact with a host of organisms and parasites completely unfamiliar to western human physiology and medicine - not to mention the insecticides, chemicals, and drugs aimed at combating those agents to keep troops fighting in the field. In general, no matter where it is, war is just not a very healthy place.

There has been a common perception in recent years which cites Agent Orange, and Agent Orange alone, as the culprit responsible for a diverse and extensive list of unexplained disorders among Vietnam veterans. The impetus behind the major studies authorized by the Congress, costing tens of millions of dollars, initially focused only on Agent Orange as the chief villain. The legislation before us today does the same thing. It calls for a presumption for compensation attributing illness to exposure to Agent Orange, and only Agent Orange, for certain disabilities, both common and rare, which could surface in the Vietnam veteran population at any time. We know that dioxin is not good for you. But we do not know from the studies which serve as the basis for this legislation, whether or not those Marines who died of non-Hodgkin's lymphoma or lung cancer were even exposed to Agent Orange. But, if we presumed that they were, based on the results of the VA's mortality study, should the Congress only authorize compensation for those specific disabilities for only those Marine Corps veterans who served in Vietnam between July 4, 1965, and March 1, 1973, as the data base in the study demonstrated. Would that be fair?

Senator Murkowski's bill, S. 1692 would rightly allow the VA the opportunity to rebut a veteran's claim based on an analysis of the veteran's service record to determine if that veteran served in an area where potential exposure to Agent Orange was possible. While this a proper control to the legislation, we do not believe that available information is reliable enough to make such an exposure determination effective or reasonable. The attempt to track exposure to Agent Orange is based on a trail that has long grown too cold.

In PVA's opinion, the only way we can solve this puzzle is to treat Agent Orange as one among many potentially harmful experiences and elements to which Vietnam veterans were potentially exposed. If there are groupings of disabilities for which compensation is not now authorized which appear at statistically significant levels for the entire Vietnam veteran population, we should proceed to provide a mechanism to authorize that compensation. In our opinion, that was the impetus behind CDC's Vietnam Experience study which will be released at this hearing. We look forward to reviewing the preliminary results of that study today.

Mr. Chairman, all of PVA's members have incurred spinal cord injury, disease, or dysfunction. We see every day and understand well the pain and suffering that the long-term consequences of catastrophic, life-threatening disabilities. We know what effects disability can have on individual veterans and their families. We are advocates for the veteran. We strongly believe the government has a definitive obligation to make restitution, and care for those who have served in defense of this nation. We have the deepest concern for those Vietnam veterans who currently suffer debilitating and life-threatening diseases from unknown causes which they suspect to be associated with exposure to Agent Orange. But we know far too well that accident, injury or disease is never anticipated or expected nor is it often easily explained when it strikes.

The VA is currently authorized by law to provide priority, Category A, inpatient medical services for those veterans. We believe this to be entirely proper as the scientific investigation into the potential effects of exposure to Agent Orange continues. PVA would strongly suggest extending entitlement to Category A outpatient service to these same veterans in the same fashion that this Committee and the Congress approved outpatient entitlement for other veterans in the highest VA eligibility categories through the passage of H.R. 2616. However, we do not believe that a connection should be drawn to provide service-connection for exposure to Agent Orange for the disabilities listed in the legislation before us today.

Over the past 15 years, deep concerns have been raised within the entire Vietnam veteran population over the potential long-term consequences of exposure to Agent Orange. Certainly, the purpose of spending millions of dollars in an investigatory effort to study the health status of the Vietnam veteran population and any possible adverse effect of Agent Orange exposure has been to see if compensation is warranted. But in our opinion, this search has also been launched to either allay or confirm the deep concerns for thousands of Vietnam veterans who have harbored concerns regarding the potential effects of dioxin.

By far, the vast majority of epidemiological evidence, to date, has shown that Vietnam veterans, as a group, are not at higher risk to certain systemic diseases than those veterans who did not serve in Vietnam. While we would support any effort to provide compensation for Vietnam veterans if scientific evidence could confirm that compensation was warranted, based on solid and corroborated scientific evidence, we would do so. However, proceeding to provide that compensation on the basis that science failed and that we might never be able to solve this puzzle seems unreasonable to us.

Proceeding with compensation based only on a supposition, no matter how compassionate, does little to allay the concerns of Vietnam veterans, as a group, who seek a definitive answer from their government. It would be easy, and, in our role as veteran's advocates, totally understandable, to support such compensation now. But in doing so, we would only be confirming and promoting suspicion which provides no real answer to the Agent Orange question or the health concerns of Vietnam veterans at all. This could, very well, actually release some of the pressure to continue this important overall search to its conclusion.

VETERANS OF FOREIGN WARS OF THE UNITED STATES

OFFICE OF THE DIRECTOR

STATEMENT OF

GORDON R. THORSON, SPECIAL ASSISTANT
NATIONAL LEGISLATIVE SERVICE
VETERANS OF FOREIGN WARS OF THE UNITED STATES

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

WITH RESPECT TO

AGENT ORANGE AND THE IMPACT OF CURRENT LEGISLATION
S. 1692 AND S. 1787

WASHINGTON, D. C.

MAY 12, 1988

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

The Veterans of Foreign Wars is made up of 2.2 million combat veterans and 700,000 ladies in our Ladies Auxiliary, giving us a combined voice of 2.9 million. I have the privilege of representing the viewpoint of our organization at this extremely important hearing. Our testimony will center on the Agent Orange issue, discuss current legislation, and suggest possible improvements to current legislation.

The Veterans of Foreign Wars steadfastly believes that immediate steps must be taken to address the continuing needs of veterans exposed to Agent Orange and suffering residual disability as a result of dioxin retained in their bodily systems.

It has been over 10 years since public attention was first focused on the possible health effects or dangers caused by exposure to a deadly toxin found in defoliants used extensively during the Vietnam War. Vietnam veterans became aware of the defoliant commonly known as Agent Orange and the toxic

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nature of the dioxin contained within that substance. Much concern and outrage was expressed back in 1978 and that same concern and outrage continues to grow. What has been done during all this time to resolve the issue:

- Over $130 million has been spent on research and studies.
- Numerous congressional hearings have been convened.
- Advisory committees have been formed.
- Countless meetings have been conducted.
- Tons of paper covered with statistics and other data have been generated.

But what has actually been accomplished that will directly impact individual veterans:

- Vietnam veterans now have access to medical treatment for any disability or disease thought to be a result of Agent Orange exposure.
- An Agent Orange physical examination and registry were made available to gather information and help find answers for the many concerns expressed by veterans.
- The medical and scientific community has identified dioxin (2,3,7,8 TCDD) as the compound most responsible for causing adverse health effects.
- The Veterans Administration has officially acknowledged widespread Agent Orange exposure in Vietnam veterans: 3.311a(b) Code of Federal Regulations (CFR) states that: "A veteran who served in the Republic of Vietnam during the Vietnam Era shall be presumed to have been exposed to a herbicide containing dioxin while in Vietnam."

- Service-connected disability has been allowed for chloracne manifested not later than three months from the date of exposure.
- A blood test has been developed and tested that can accurately establish the level of dioxin retained in a human subject.

Through the years the veteran public has been inundated with conflicting reports and seemingly endless delays. Much time and millions of dollars have been expended pursuing perfect understanding, coupled with scientific certainty as to the residual effect of Agent Orange on veterans exposed to its deadly toxin, dioxin. Have Vietnam veterans been given answers to their questions or just more questions to be answered?

It is useless to list or even comment further on the tons of paper already generated by the numerous studies and extensive research. The VFW believes that it is time to separate the wheat from the chaff. Individual veterans exposed to Agent Orange want some answers. They want to know what their government intends to do about the physical disabilities they must endure as a result of their exposure to dioxin.

Two bills are presented for discussion today, S. 1692 introduced by Senator Murkowski and S. 1787 introduced by Senators Daschle, Kerry, Simon, Wirth, Heinz, Specter, and Pressler. Neither bill enjoys a long list of cosponsors, however, support will undoubtedly increase as a result of today's hearing.

S. 1692, would amend Title 38 of the United States Code to allow a rebuttable service-connected presumption for disease or death as a result of non-Hodgkin's lymphoma.

S. 1787 would amend Title 38 of the Unites States Code to allow a nonrebuttable service-connected presumption for certain disabilities.

S. 1787 offers a list of presumptions to include: (1) non-Hodgkin's lymphoma, (2) lung cancer manifested within 25 years of the veteran's last day in Vietnam and (3) disabilities that are reasonably associated with suppression of the immune system as a result of exposure to dioxin or other toxic herbicides. S. 1787, takes the additional step of establishing a scientific committee to survey existing and ongoing scientific data. This Committee would be charged with listing any disabilities reasonably associated with exposure to dioxin or other toxic herbicides and would continuously upgrade and enlarge the disability list as scientific knowledge of herbicide exposure becomes more complete. S. 1787, would further direct the Veterans Administration to compile and analyze all clinical data obtained since November of 1981 and report their findings to the Senate and House Veterans' Affairs Committees.

The Veterans of Foreign Wars was among the very first to call for a timely study of the effects of dioxin on veterans. This occurred during the first congressional hearing held on this issue before the Subcommittee on Medical Facilities and Benefits of the House Veterans' Affairs Committee on October 11, 1978. The VFW also requested medical care for veterans thought to be exposed to Agent Orange and compensation for any disability resulting therefrom. Every August the voting delegates of our organization meet in National Convention and pass resolutions that become the VFW mandates for the following year. Our first Agent Orange resolution was advanced in 1979 and we have since continuously called for a thorough, accurate, yet expeditious resolution of this controversial issue. Our most recent VFW Resolution Number 628 entitled "Herbicide Exposure," calls for liberalizing criteria for the disposition of Herbicide related claims (copy Resolution Number 628 attached). The VFW supports the intent of both S. 1787 and S. 1692, either bill would liberalize the current criteria used in the disposition of herbicide related claims and help shift the burden of proof to the United States government. Though we support both bills, S. 1787 is a much more comprehensive bill that would provide additional presumptives, ongoing dioxin studies, annual updates of the presumptive disability list and require continuing VA participation. We do question the need to exclude the proposed presumptions from normal VA scrutiny, Section 3(b) of S. 1787.

Whenever presumptive disabilities are allowed, the government must set aside the normal rules of evidentiary development in favor of a more compassionate method of establishing service-connected compensation. However, good common sense should not also be set aside; if there is substantial evidence clearly showing that the claimant was not disabled as a result of military service, then he shouldn't receive compensation. The VA must be given reasonable guidelines to use while adjudicating these special presumptive allowances, thereby preserving some integrity within the VA compensation system. The burden of proof should be placed on the VA, if they can prove, beyond a reasonable doubt that a claimant's disability is not a result of military service then the VA should be allowed to act on that evidence. The VFW believes that all veterans deserving service-connected compensation, as a result of dioxin exposure, should receive their just entitlement; we could not condone awarding public funds to unqualified beneficiaries.

It is time for the Congress to organize the accumulated results of 10 years of study and apply this knowledge to legislation that would directly impact the individual veteran seeking service-connected compensation.

The VFW believes there is an interim solution available to help alleviate some veteran concerns while continuing to develop a reasonable and responsible method of establishing service-connected compensation on a presumptive basis.

So far the studies have focused on examining aggregate groups of our veteran population and the results reflect only general conclusions. Little has been done to target the individual veteran on a case-by-case basis. We believe there is enough scientifically valid information and evidence available to formulate and apply a plan that could ultimately resolve this issue.

Current regulations, evidence and knowledge allow that:

- Agent Orange used in Vietnam was contaminated with a deadly toxin called dioxin (2,3,7,8TCDD).
- Dioxin is one of the most toxic chemicals known to man and extraordinarily low dosages can even prove fatal to certain animals.
- Dioxin is known to cause or be associated with certain disabilities.
- The VA acknowledges that all in-country Vietnam veterans are presumed exposed to dioxin while in Vietnam.
- Scientific and technological advancements have recently made it possible to accurately measure the level of dioxin present within the human body by extracting and analyzing blood plasma.

After considering the above, it appears that the technology for detecting and measuring dioxin is progressing much more rapidly than our ability to understand the biological significance of exposure and retention of dioxin in the human system. It is not how much exposure occurs but how much of the dioxin is retained in the body of the victim. The dose of dioxin received and retained is the important factor and that thought brings us precisely to the major point of this dissertation:

We advocate that any in-country Vietnam veteran who claims residual disability as a result of Agent Orange exposure should be given a blood serum test. If the blood test shows an inordinate amount of dioxin (2,3,7,8TCDD), steps should be taken to evaluate the veteran's disabilities and allow service connection as warranted. If the test does not show a specified level of dioxin, the veteran should be informed of same and appropriate action taken.

We assert that **DIOXIN** is commonly accepted as the link between Agent Orange exposure and residual disease or disability. Any evaluation of a veteran for presumptive Agent Orange disability should logically include a test to determine the level of dioxin absorbed and retained in his system.

The current language of S. 1692 and S. 1787 could logically be combined, edited, and expanded to include a dioxin test, thereby becoming a significant and effective single piece of legislation. The amended legislation would incorporate all language held in common between S. 1692 and S.1787; excluding lines 10 through 15 on page 3 of S. 1692 as this language is contrary to what has already been achieved and allowed under section 3.311 a(b) of the United States Code of Federal Regulations; also exclude lines 16 through 20 on page 3 of S. 1787, as this language runs counter to the longstanding and reasonable assertion that a veteran should never receive compensation for disabilities known to be nonservice connected.

We further suggest that the above combined legislation could be improved by adding:

- A section requiring a blood serum test and/or an adipose tissue test to firmly establish the claimant's retained dosage of dioxin.

- A section requiring a nonprofit scientific organization to not only build and maintain a valid list of dioxin related diseases, but also determine what constitutes an unacceptable level of dioxin. The report should clearly set forth guidelines for interpreting the results of blood plasma dioxin testing.

In conclusion the VFW would like to assert that we are solidly behind a reasonable course of action that would finally allow individual veterans an opportunity to successfully pursue and establish service-connected compensation. Any veteran who believes that he was exposed to Agent Orange should be tested and if:

1) The blood serum test or adipose tissue test shows an abnormal level of dioxin, and
2) the military record shows in-country service in Vietnam, and
3) the veteran has a residual presumptive disability that can be attributed to retained dioxin, then...

after considering the above three factors and they prove positive, it is reasonable to award service-connected disability benefits.

We call for and will support legislation designed to give fair, compassionate, and deserving treatment to veterans found suffering from the residual effects of dioxin exposure.

Resolution No. 628

HERBICIDE EXPOSURE

WHEREAS, herbicides, the most common known as "Agent Orange", were utilized in great quantities in Vietnam; and

WHEREAS, many Vietnam veterans were exposed in varying degrees to these toxic defoliants; and

WHEREAS, the Veterans of Foreign Wars is on record supporting the premise that the exposure to herbicides may cause certain health defects; and

WHEREAS, the Centers for Disease Control has been contracted by Congress to conduct studies into the health effects of herbicides on Vietnam veterans; and

WHEREAS, good conscience and equity mandates that Vietnam veterans be given benefit of doubt in the prosecution of their claims until this study is completed; now, therefore

BE IT RESOLVED, by the 88th National Convention of the Veterans of Foreign Wars of the United States, that we continue to endorse and support liberalizing criteria for the disposition of herbicide related claims, to include placing the burden of proof for the award of disability compensation on the U. S. Government rather than on the veteran.

Adopted by the 88th National Convention of the Veterans of Foreign Wars of the United States, held in New Orleans, Louisiana, August 14-21, 1987.

Resolution No. 628

Vietnam Veterans of America, Inc
2001 S St., NW
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STATEMENT OF

VIETNAM VETERANS OF AMERICA, INC.

Presented By

MARY R. STOUT
PRESIDENT

With The Separate Supporting Scientific Views Of

THOMAS A. GASIEWICZ, Ph.D.
ASSOCIATE PROFESSOR OF TOXICOLOGY
DEPARTMENT OF BIOPHYSICS
UNIVERSITY OF ROCHESTER

before the

SENATE VETERANS AFFAIRS COMMITTEE

on

AGENT ORANGE

MAY 12, 1988

I. INTRODUCTION

Mr. Chairman and members of the Committee, the Vietnam Veterans of America, Inc. (VVA) appreciates this opportunity to present its views on the legislation under consideration at today's hearing to provide disability compensation for illnesses associated with exposure to herbicides containing dioxin, the contaminant in Agent Orange and other herbicides. As this Committee knows, the VVA has been deeply involved in this issue for many years. Just as surely, this Committee is also well aware of our dissatisfaction with the VA's responsiveness to veterans deeply troubled by the uncertainty of their current and future health status, given their suspected exposure to toxic herbicides in the Republic of Vietnam.

Apart from what we have come to believe is a clear bias by the VA against awarding compensation for disabilities associated with exposure to dioxin, the history of scientific studies conducted to explicitly ascertain the health effects of dioxin exposure has been checkered at best. Since Congress first directed the VA in 1979 to plan for and conduct an epidemiologic study of persons exposed to herbicides in Vietnam, the VA would have us believe that we are still no closer to being scientifically certain about the effects of exposure than we were nine years ago. Indeed this uncertainty is precisely what the VA seems bent on maintaining in order to withhold compensation in the absence of a strict cause-and-effect relationship between exposure and disease.

In the interim, the study directed in 1979 by P.L. 96-151 was transferred to the Centers for Disease Control (CDC) in 1982. This was done because of the VA's slowness in starting up the study and the agency's initial disavowal of any potential harm from exposure to dioxin. Unfortunately, in 1987 the CDC recommended that the long-awaited exposure study be dropped because of difficulties in determining exactly which veterans were in areas sprayed with herbicide defoliants and at what exposure levels.

In 1981, the Congress passed and the President enacted P.L. 97-72. This legislation offered partial relief to veterans by authorizing health care for diseases that may be associated with dioxin exposure. Since then the VA has given a series of conflicting reports on the numbers of veterans treated for such diseases. We were astounded in 1987 to hear from Dr. Barclay Shepherd that 41,000 inpatients and 1.1 million outpatients had been treated under this law. Even more astounding was the revelation, verified by VA officials, that many Vietnam veteran visits were counted in this number regardless of the veteran noting their concerns of an Agent Orange related illness.

Through a series of correspondence with the VA during the summer of 1987 we were assured that this practice would cease and were given new numbers. The outpatient visits number was cut by more than one-third yet documents recently received by VVA indicate 37,000 inpatients and 4.1 million outpatients have been treated for Agent Orange related illnesses. We view this count as a public relations effort that probably has little or no validity. Additionally, we are unaware of any analyses of the data accumulated as a result of providing this care. We have to believe that it should have occurred to someone at the VA that evaluating this data could provide important information in ascertaining what, if any, commonality exists in the diseases of those veterans treated. This information might have been useful in specifically targeting studies of relationships between dioxin exposure and specific disease.

P.L. 97-72 also expanded the scope of the CDC studies on dioxin exposure by authorizing an experience study in addition to the exposure study. The experience study contained two parts. The first was a mortality study and the second was to be a morbidity study. In neither studies did the CDC determine whether the study subjects were exposed to dioxin. This is because exposure was not a factor in either of these studies. It is indeed disappointing that the CDC has seen fit to await its release of the study's finding at today's hearings before providing the veterans service organizations with a briefing which is scheduled for later this afternoon. Nevertheless, we look forward to the results of that study.

In 1984, Congress passed the Veterans Dioxin and Radiation Exposure Compensation Standards Act, P.L. 98-542. The stated purposes of the Act were to ensure that temporary benefits be immediately available to certain veterans and surviving families and that disability compensation be provided on a permanent basis to veterans who were exposed to dioxin and suffer disabilities incurred as a result of military service in Vietnam. The new law contained the finding that some evidence existed to link chloracne, porphyria cutanea tarda and soft tissue sarcoma to dioxin exposure. As a result, Congress ordered the VA to propose new regulations setting forth the criteria for resolving claims relating to exposure to herbicides. The Congress also directed the VA to propose guidelines for VA's evaluation of scientific studies which would be used to determine which diseases could be assumed to result from service in Vietnam. These diseases would then be compensable.

As part of the interim benefits to be provided, disability compensation was to be made available to veterans who served in Vietnam and who developed chloracne or porphyria cutanea tarda within one year of leaving Vietnam. These benefits were to commence between October 1984 and September 1986. Although the VA has acknowledged that several veterans have been afflicted with these conditions, no benefits were ever awarded. Additionally, the VA has admitted that no veteran has ever received any compensation for any disorder claimed to be the result of dioxin exposure. This is perhaps not surprising since the only disease the VA currently acknowledges as possibly resulting from exposure to dioxin is chloracne. This disorder is compensable, but only if its appearance can be documented as having become manifest within three months of leaving Vietnam.

From our perspective over the course of the entire period of debate on this issue, the VA can no longer be trusted. The agency was forced to relinquish responsibility for the original Agent Orange study because of foot-dragging and its widely perceived bias against any connection between exposure and disease. As we discuss below, the VA has failed to fully and properly implement P.L. 98-542. Thus, the agency can no longer be trusted to carry out Congressional intent on this issue.

About all that has shielded the VA from more widespread charges of recalcitrance on this issue than have already been aired is the agency's insistence that there be consensus within the scientific community on a strict cause-and-effect relationship before compensation is warranted. Studies conducted by the federal government have been funded and some have been completed with varying results. Smaller scale studies have been, and continue to be, undertaken by individual states but the results of these too are inconclusive on a strict cause-and-effect relationship.

The VVA strongly believes the studies must continue, but we even more strongly believe that it is improper to await scientific consensus on a strict cause-and-effect relationship before providing disability compensation to veterans with diseases reasonably associated with dioxin exposure. After all of the time that has already passed since the enactment of P.L. 96-151, it seems clear enough to us that scientific consensus within the epidemiologic community on an absolute cause-and-effect relationship will not be reached within the foreseeable future. We therefore believe that it is now time to begin resolving this issue by making the political choices necessary to provide compensation for disabilities presumptively associated with dioxin exposure. This is the approach taken in the Senate and House on April 25 and May 2 of this year, respectively, in approving compensation legislation for ionizing radiation-exposed veterans and it is the approach that must be taken now for dioxin-exposed veterans.

During debate on the atomic veterans legislation, for example, House Veterans Affairs Committee Chairman G.V. (Sonny) Montgomery put the case for making a political decision succinctly by stating that the evidence holding a direct cause-and-effect relationship between radiation exposure and specific disease "will never be available" because "the level of exposure cannot be verified." Why it is so difficult to substitute the term dioxin exposure for the term radiation exposure in connection with affording disability compensation for Agent Orange-exposed veterans is a genuine mystery.

As this committee knows, P.L. 98-542 represented a departure from earlier legislation. It was designed to go further than authorize scientific studies, first by VA and later by the CDC. That law represented a balance between the need for a political decision to be made as a first step in resolving this issue and the VA's expressed opposition to being forced into policies based on political pressure rather than scientific evidence.

Unfortunately, Mr. Chairman, had the VA lived up to its mandate by fulfilling its obligations under the law's Congressional intent, today's hearing might not have been necessary. The VA failed to live up to its mandate, the issue remains unresolved and it is now time to recognize that the VA's objections to taking the political decision-making steps needed to begin resolving this matter must be ignored. Sadly, the VA's historic performance on this issue has rendered irrelevant its input today. The VA and this Administration may indeed threaten a veto of compensation legislation just as a veto has been threatened against the radiation compensation legislation passed very recently. Nevertheless, we are prepared to take that risk.

II. THE VVA'S LAWSUIT

The purpose of P.L. 98-542 was "to ensure that Veterans Administration disability compensation is provided to veterans who were exposed during service in the Armed Forces in the Republic of Vietnam to a herbicide containing dioxin... for all disabilities arising after that service that are connected, based on sound scientific and medical evidence, to such service." P.L. 98-542 mandated that the VA promulgate regulations for handling Agent Orange disability compensation claims. The regulations were to be based upon scientific and medical evidence which would be evaluated by an independent advisory committee, composed mostly of scientists. This committee was supposed to review the pertinent scientific studies on the health effects of exposure to dioxin and give advice and recommendations to the VA based on their review of the studies.

Pursuant to the Act, the VA set up the VA's Advisory Committee on Environmental Hazards. The Committee is composed of fifteen members, eleven of which are scientists. It is the role of the Advisory Committee to give advice to the Administrator on whether there is sound scientific or medical evidence indicating a connection between any diseases and exposure to herbicides containing dioxin.

In April 1985, the VA published proposed regulations for compensating veterans for Agent Orange-related diseases. The regulations provided for no disability compensation (except for interim benefits) for any Agent Orange-related disease, except for chloracne if manifested within three months from leaving Vietnam.

In April 1985, the VA's Advisory Committee met for the first time. No scientific studies were reviewed during this meeting. At their next meeting, in June 1985, the Committee reviewed a total of seven (7) studies related to the health effects of dioxin. Even though the VA had been specifically directed to look at whether porphyria cutanea tarda and chloracne were linked to dioxin exposure, the Committee did not review even one study whose specific subject is either of these diseases.

After its review of a grand total of seven studies, the Committee decided that the VA regulations disallowing presumptive service connection status for any disease except for chloracne were based in sound scientific and medical evidence. The VA's regulations were finalized in August 1985. After its June 1985 meeting, the Advisory Committee did not meet again until the spring of 1986. Since that time, the Committee has met approximately twice a year and continues to meet to this day. The Committee has not recommended that any diseases be given presumptive service connected status as related to exposure to dioxin.

The VA's implementation of P.L. 98-542 has been fraught with deficiencies. The VA has failed to comply with the mandates set forth by P.L. 98-542 in several respects. This failure to comply with the Congressional mandates is the subject of a lawsuit that the VVA has brought against the VA. Among the violations of P.L. 98-542 are the following:

(1) As stated above, the VA Advisory Committee, which was charged to review the pertinent scientific studies relating to the health effects of exposure to herbicides containing dioxin, reviewed as a group only a total of seven studies before recommending to the Administrator that the VA should not grant service connected status to veterans for any Agent Orange related disabilities except for chloracne.

(2) The VA did not provide the Committee with adequate administrative or financial support to conduct a thorough review of the scientific studies. From the beginning, the Committee was set up to meet once or twice a year, not nearly enough time to do a thorough review of the scientific literature. There are over one thousand scientific studies pertaining to the health effects of exposure to dioxin.

(3) Prior to the adoption of the final regulations, the Scientific Council of the Committee did not submit any reports to the VA on the pertinent scientific studies related to dioxin, as it was required to do.

(4) Neither the VA nor the Committee has enunciated a standard of proof by which the studies should be evaluated; that is, there is no clear directive to the Committee as to how much evidence is enough to warrant recommending compensation for a specific disease.

(5) The VA and the Committee are using a strict "cause and effect" test by which to judge whether or not a disease should be granted service connection based on exposure to Agent Orange; that is, unless and until the science shows that dioxin causes a specific disease in humans, compensation will not be granted. This test is being used despite the fact that other diseases have been granted service connection status without proof of a cause and effect (i.e., multiple sclerosis).

(6) The VA Advisory Committee failed to keep accurate and complete minutes of the matters discussed at the meetings.

(7) The VA failed to make evaluations of the findings of scientific studies as required by the Act and to publish such evaluations in the Federal Register.

(8) The VA did not abide by the policy that reasonable doubt be granted in favor of the veteran in promulgating its Agent Orange regulations.

III. DIFFERENCES BETWEEN THE PROCESS USED BY VA AND THE EPA IN ASSESSING THE EFFECTS OF DIOXIN

That the process by which the VA Advisory Committee reviewed the science on the health effects of dioxin was defective becomes glaringly apparent when compared with the process used by the Environmental Protection Agency when it undertook a similar project.

In the early 1980's, the EPA decided to assess the likely adverse health effects in humans, if any, of exposure to dioxin by preparing a health assessment document. Such health assessment documents are often created by the EPA in order to determine safety levels of compounds in the air pursuant to the Clean Air Act.

The EPA's charge was remarkably similar to the charge to the VA Advisory Committee: determine what, if any, are the human health effects of exposure to dioxin. One would assume, therefore, that the method by which both entities attempted to answer this question would be somewhat similar. However, the procedures used by the two groups were as different as night and day.

When the EPA project was started, a thorough and exhaustive literature search was done to locate all of the scientific studies on dioxin. This involved several bibliography searches in libraries and turned up literally thousands of studies. The abstracts for all of these studies were read, and more than seven hundred were chosen as the most pertinent ones, including hundreds of animal studies.

Next, persons were selected who would act as the authors of the health assessment document. The EPA chose as authors persons that were known to be well versed in the dioxin issue. Each author was directed to read all of the seven hundred studies before he or she wrote a particular assigned section of the document.

When all of the authors had read the studies and written the drafts of their sections, the sections were compiled into a draft document. The document then went through peer review. A group of more than thirty scientists from a variety of different fields, including academic, industrial, and political groups, were chosen to act as the peer reviewers. The peer review group examined and discussed the document in detail, until all members were satisfied with the final draft. The EPA then released the final version of the health assessment document in September 1985. The EPA health assessment document concludes that dioxin is a probable human carcinogen.

The EPA's thorough and thoughtful process by which it examined the literature on the human health effects of dioxin is in sharp contrast with the procedures of the VA's Advisory Committee, which was created to do exactly the same thing. For example:

(1) Rather than search the literature for the thousands of scientific studies relating to health effects of dioxin, the VA Advisory Committee went through an ad hoc, informal study selection process.

(2) Instead of reviewing the studies on dioxin and then selecting a meaningful set of the pertinent studies, the VA Advisory Committee reviewed only seven studies before recommending to the VA that its regulations regarding Agent Orange disability compensation were based in sound scientific and medical evidence. Even though the Advisory Committee has now been meeting for nearly three years, it still has not reviewed more than a small fraction of the number of studies reviewed by the EPA.

(3) Rather than review animal studies, which are the only truly controlled experimental studies that examine the biological effects of dioxin, the VA did not give its Advisory Committee any animal studies to review because they were deemed to be not relevant. This is particularly egregious because the few human studies that the Committee has looked at are often denounced as flawed and therefore of little value. For example, most if not all studies of persons exposed to dioxin are unable to accurately determine the extent and amount of exposure, thus putting the results into question. In other words, the Committee will look only at human studies, yet their review of human studies evinces the attitude that no human study will ever be scientifically valid enough to act as a basis for granting compensation. Veterans have been truly put into a Catch-22 situation by the VA whose bottom line agenda seems to be that compensation will never be granted for

any disease.

The VA has had three years to correct these flaws in their procedures. Although there have been some changes since the initiation of VVA's lawsuit, these changes are far too little and too late. The VA and its Advisory Committee should not be put in charge of making the determination regarding Agent Orange compensation. They have proven that they cannot or will not get the job done properly.

IV. RANCH HAND

Last February a new Air Force report criticized some of the 1984 findings in the Ranch Hand study, whose preliminary conclusions have been widely used by opponents of disability compensation for dioxin-exposed veterans to derail a legislative solution. This latest report, written by Dr. Richard A. Albanese, M.D., constitutes an important break from past Ranch Hand reports in two respects. First, it includes a discussion of animal studies in great significance for the first time and second it states, for the first time, that the Ranch Hand study results show pathological effects in several biological areas among Ranch Handers.

A. Background of Ranch Hand

The Ranch Hand study compares the Ranch Handers (approximately 1200 Air Force personnel who were directly involved in the handling and spraying of Agent Orange in Vietnam) to other Air Force personnel who flew in, out of, and around Vietnam but were not part of Operation Ranch Hand. The study looks at the morbidity (illness) and mortality (death) rates of both the control (Ranch Handers) and the comparison (non-Ranch Handers) groups. Prior to February 1988, reports from the Ranch Hand study alleged no real differences between the two groups in either area. Actually, there were a few differences, but these were explained away or were not seen as statistically significant. The Ranch Hand report has until recently been cited as showing that there are no serious ill effects from Agent Orange.

B. Why the Original Ranch Hand Study is Viewed as So Important

The government has praised the Ranch Hand study as the most significant study in the area of determining human health effects of exposure to Agent Orange. Dr. George Lathrop, who was in charge of the Ranch Hand study, has stated that the Ranch Hand study is the most important Agent Orange study because the only group of Vietnam veterans that are known, with a fair degree of certainty, to have been exposed to Agent Orange were the Ranch Handers. Studies of other Vietnam veterans such as ground personnel aren't as good, according to him, because it is difficult to determine who was and who was not exposed. The Ranch Handers, however, were supposed to have been definitely exposed. In addition, the Ranch Handers were presumably exposed to much higher levels of dioxin than were ground troops. Dr. Lathrop has stated that Ranch Handers were exposed to at least a thousand times more Agent Orange than were ground troops. Where these figures come from, however, is unclear.

C. Criticisms of the Study

Without being scientists, it is difficult for VVA officials to describe in any great detail how or why the Ranch Hand study is flawed. However, there are two main criticisms of the study that have been expressed by several scientists we have spoken with.

(1) Exposure Index. There are many factors within the study which make it extremely difficult to measure the exposure to dioxin of the Ranch Handers. All exposure indexes are estimates at best. The February 1988 Update comments on this major flaw.

(2) Power. Since the number of Ranch Handers is so small, it would be very difficult, if not impossible, to use the findings of the study to determine whether there is an increased risk of certain rare cancers and other diseases. The February 1988 Update also comments on this problem.

D. February 1988 Update Overview

The basic mission of the February 1988 Update is to examine the degree to which the Ranch Hand findings are compatible with other experimental (animal) and epidemiologic findings on TCDD.

For each category of biological effect, Dr. Albanese first sets forth the results of some animal studies in that area. For example, in "Reproduction", he describes the results of many animal studies, all of which suggest that dioxin has an adverse reproductive effect. The presentation of the animal data implies a strong suggestion that dioxin does have a toxic effect in that particular area.

Dr. Albanese next describes the Ranch Hand findings in that particular area. However, the Ranch Hand findings are fairly weak by contrast with the animal studies. Dr. Albanese generally omits comment on the significance of the Ranch Hand findings, except to state whether they are "statistically significant". However, he does comment that the Ranch Hand findings may be weak because of the low power and because of the imprecision of the exposure statistics.

E. A Review of the February 1988 Update

1. Introduction

This report reviews findings of the first 1984 morbidity Ranch Hand update and laboratory and other epidemiologic studies in eleven clinical areas. In six of these areas, statistically significant group differences occurred, and in five of these six instances group differences showed Ranch Handers in poorer health than non-Ranch Handers.

2. Methods

Dr. Albanese goes through the study design and then goes into detail about the inference concerning herbicide causation of ill health. Because the Ranch Hand study is of an unplanned environmental exposure type, it does not follow an experimental design. Rather, it is an observational study which by definition contains the flaw that arises from an inability to select out confounding factors, factors that may affect the differences between the two groups.

The exposure index in the Ranch Hand study is mostly guess work. Estimates of herbicide effect, according to Dr. Albanese, "must be viewed with great care due to the possibility of many confounding factors." The Ranch Hand study applies theater-wide spraying to a single individual and assumes all individuals in a job category were equally exposed. It does not take into account hygiene data, which is unavailable, or the possibility that higher exposures occurred in the lower ranks of the Ranch Hand cohort.

The 1988 Update next sets forth in broad terms the physical, laboratory and psychological examinations that the Ranch Hand study participants were put through.

3. Results

i. Morbidity

The baseline morbidity report in the Ranch Hand study had 13 primary clinical chapters. More than 190 clinical variables were tabulated. In this Update only a subset of those variables are discussed, specifically in areas where there is laboratory data available that can be compared with the Ranch Hand findings.

The Ranch Hand study has "virtually no power for detecting relative risks" for rare diseases, but has good power for detecting relative risks for common diseases.

ii. General Health

- Weight Loss

Dr. Albanese sets forth several animal studies that show a weight loss effect from TCDD. The Ranch Hand study shows no statistically significant differences between the Ranch Handers and the comparison group in body weight. Also, there was no relationship between body fat and the exposure index.

- Neoplasia (cancers)

Different animal studies have indicated that TCDD is a carcinogen, a cocarcinogen, and an anti-carcinogen. The Ranch Hand studies show a higher incidence of both skin cancer and systemic cancer among the Ranch Handers.

- Reproduction

Dr. Albanese describes various animal studies, many of which show a reproductive effect in animals exposed to TCDD. Similarly, the Ranch Hand group has a statistically significant increase in birth defects. The Ranch Hand report asserted that birth defects such as minor skin lesions accounted for the birth defects excess in Ranch Handers' children. It also asserted that over-reporting by overly sensitized participants could account for the excess. Dr. Albanese states that these assumptions are no longer necessarily valid. In other words, the excess must be taken more seriously.

- Neurological Findings

Although neurological symptoms have been described in workers following industrial accidents involving TCDD, and animal experiments have also shown neurological changes, there are no statistically significant differences in the Ranch Handers to date.

- Psychological Assessment

Both animal and human studies show that TCDD provokes irritation, anger, fatigue, and or inability to concentrate. The Ranch Hand study showed all Ranch Handers to have more problems with these and other psychological symptoms, including isolation, depression and anxiety. The differences are statistically significant. Those with higher education (and therefore more likely to have been officers) did not suffer psychological symptoms as severe as those with lower education. No data were adjusted for combat stress.

- Hepatic Examination (Liver)

Dioxin has been associated with hepatotoxicity. Several animal and some human studies showing liver effects are discussed. An explanation of the Ranch Hand groups follows the discussion of the studies which states that there are generally no differences between the groups except in a few specific areas.

- Dermatological Findings

TCDD is known to cause chloracne. Sometimes chloracne resolves itself in a short period of time, other times it may persist for years. In the Ranch Hand study, no active cases of chloracne were found in either group.

- Cardiovascular System

There are some animal studies that suggest a cardiovascular effect from TCDD. However, in the Ranch Hand study no statistically significant differences were found except for abnormal pulses which were higher in non-black Ranch Handers. There were no differences between black Ranch Handers and black non-Ranch Handers.

- Immunological Effects

Animal studies show immunological effects from TCDD. The Ranch Hand study showed no statistically significant differences.

- Endocrinological Effects

Animal studies show endocrinological effects from TCDD. The Ranch Handers have both negative and positive effects in this area.

- Mortality

Studies with animals show increased mortality with large doses of TCDD. No animal studies have been done to show the possibility of life abreviation resulting from very low doses of dioxin over an extended period of time. There is no statistically significant difference between the Ranch Handers and non-Ranch Handers for mortality. However, there is a marked difference between officers and enlisted men with higher death rates for enlisted men.

VI. S.1692 AND S.1787

On September 17, 1987, upon introduction of S.1692, Senator Murkowski stated that "The evidence is not perfect; but it will never be perfect. Our understanding of cause and effect is still incomplete, but we will never have a complete understanding of disease and its causes.

"The essence of leadership is to know when the data is adequate to act.

"Leadership is a willingness to take action in the face of incomplete and imperfect data rather than accepting the paralysis inherent in a never ending wait for perfect understanding.

"The search for answers must continue; however, the constant desire for just one more study should not be an excuse for inaction."

These sentiments couldn't be more eloquently stated as a summation of the VVA's position even if we had written them ourselves. While the legislation introduced upon making these statements falls short, we have noted in Senator Murkowski's further remarks on September 17 that the measure introduced was requested by the DAV. It is our sincere hope that much stronger legislation, consistent with Senator Murkowski's definition of leadership, will be supported this year.

In essence, S.1692 provides a rebuttable presumption of service connection for one disorder, non-Hodgkins lymphoma. The justification given for selecting this particular disease as presumptively compensable is one with which we agree. The VA's own longitudinal mortality study, released last fall only after having been reported in the New York Times, showed that Marines who served in I Corps had a 110 percent greater liklihood of becoming afflicted with non-Hodgkins lymphoma than those having served outside of Vietnam. This finding is consistent with other studies that have shown an increased risk for NHL for persons exposed to the components of Agent Orange (i.e., the Kansas farmer study).

The presumption, however, is rebuttable. This means that in a future prospective claim for disability compensation under this legislation's provisions, the VA could deny service connection because of some other possible intercurrent reason for the appearance of non-Hodgkins lymphoma in the veteran claimant. We understand that this is consistent with other diseases presumed to be service connected in Title 38 which are also rebuttable. However, the VA's history on Agent Orange is replete with failure to resolve reasonable doubt as required in favor of the veteran on Agent Orange claims. As we have already pointed out in this statement, not one claim for compensation has ever been allowed for any veteran which acknowledged dioxin as the cause of disability. Of all Agent Orange claims up through to April 1, 1985, for example, 82.2 percent were denied. Those that were allowed, the remaining 17.8 percent, were granted for reasons other than Agent Orange exposure.

Our support for a non-rebuttable presumption is especially relevant with regard to our support of S.1787. That legislation, which is preferred over S.1692, allows a non-rebuttable presumption not only for non-Hodgkins lymphoma, but also for lung cancer manifesting itself within 25 years of departure from Vietnam. The presumption for lung cancer in S.1787, like that of non-Hodgkins lymphoma in S.1692, is based on the VA's longitudinal mortality study released last fall. Marines having served in I Corps had a 58 percent greater likelihood than individuals serving outside of Vietnam of becoming afflicted with lung cancer. Given the VA's history on this issue, as described above, we have to believe the VA would use a rebuttable presumption to rule out compensation for any veteran who ever smoked tobacco products, regardless of how infrequent or how long ago.

The minutes of the October 15, 1987 meeting of the VA's Advisory Committee on Environmental Hazards provide a rather telling justification for a presumption of service connection for lung cancer. During a portion of that meeting the VA's mortality study was being discussed and the subject of smoking as an intercurrent cause of higher rates of lung cancer in Marines having served in I Corps came up. One of the scientists deeply involved with the study, Dr. Kang, was asked about this finding. In providing an explanation the minutes recorded that, [H]e also agreed that smoking history would have been very valuable to include but that this type of study which relied on existing records, military records and death certificates would not include information on smoking patterns. He stated that they did attempt to look at other causes of death which might be associated with smoking (emphysema, bronchitis and other cancers associated with smoking) to determine whether they also were elevated and found ... no significant differences between veteran and non veteran Marines. In response to a question by Dr. Colton about any information that might exist about differences in exposure opportunities, Dr. Kang noted that 99% of the

Marines stayed in I Corps whereas the Army was spread out through all four tactical zones of Vietnma." (emphasis added)

The reason that a 25 year delimiting period was selected in the legislation is that even a heavy smoker would be unlikely to get lung cancer within 25 years of departure from Vietnam, unless there were some other cause such as exposure to toxic herbicides. The average age of the typical service person in Vietnam was about 20 years of age. In order to be eligible for compensation under this provision of the bill, the average claimant would have to contract lung cancer by the age of 45, a most unlikely prospect unless he or she were exposed to dioxin.

Another aspect of the legislation would require the VA to contract with an unbiased non-governmental scientific entity for the purpose of determining, on the basis of a comprehensive review of all relevant and ongoing studies, which diseases are likely to result from the presumed immuno-suppressive effects of dioxin exposure. At the end of each year the review is undertaken, a list of these diseases would be provided to the VA. The VA would then be required to compensate veterans for these diseases on a non-rebuttable presumptive basis unless the Congress passed and the President enacted legislation to the contrary within 90 days of the VA's receipt of the disease list.

The VVA believes there is good reason to proceed with compensation for immunosuppressive effects of dioxin exposure because solid evidence derived from studies conducted in animals and human tissues exist to support both a review and compensation. Although there are many species specific toxic effects resulting from dioxin exposure, including chloracne, immunosuppression is one of the most consistent findings in all mammalian species thus far examined. The data from experimental animals further indicate that the immune system is one of the most sensitive organ systems to dioxin exposure; in many cases significant alterations in immune function parameters have been observed without any other physical alterations being apparent. In addition to being more susceptible to viral and bacterial infections, the ability of dioxin-exposed experimental animals to combat the maglignant growth of tumor cells is compromised. Furthermore, limited studies that have been conducted on certain human cells of the immune system indicate the same degree of sensitivity to dioxin as the same cell type from experimental animals. Given all of these findings it is logical to deduce that immunosuppression in humans may occur at some level of dioxin exposure.

A third aspect of the legislation would require the VA to evaluate the data already at its disposal to determine whether any disease patterns can be discerned on the basis of the thousands of veterans treated by the VA under the authority granted by P.L. 97-72. It is surprising to us that this has never been done.

Mr. Chairman, rather then expecting the Committee to rely on our judgement alone in the matter of immunosuppression, we have asked University of Rochester Associate Professor of Toxicology Thomas A. Gasiewicz, Ph.D. to participate in our presentation for today's hearing. Professor Gasiewicz' primary professional interest is in the biochemical and molecular mechanisms of toxicity. The major focus of his research since 1972 has been on the toxicity of dioxin. Professor Gasiewicz also served as a member of the peer review group chosen to review the Environmental Protection Agency's (EPA) Assessment Document for Polychlorinated Dibenyo - P - Dioxins. This is the EPA document that was produced to determine the health risk to humans, the process of which was described in section III of this statement. Addended to this statement are Professor Gasiewicz' views on the immunosuppressive affects of dioxin.

STATEMENT OF
THOMAS A. GASIEWICZ, Ph.D.
ASSOCIATE PROFESSOR IN TOXICOLOGY
DEPARTMENT OF BIOPHYSICS
THE UNIVERSITY OF ROCHESTER
ROCHESTER, NEW YORK

before the
SENATE VETERANS AFFAIRS COMMITTEE
on
AGENT ORANGE

May 12, 1988

Mr. Chairman and members of the Committee, my name is Thomas A. Gasiewicz. I received my Ph.D. in Toxicology in 1977 from the University of Rochester where now I am Associate Professor of Toxicology in the Department of Biophysics. In addition to spending the past 11 years in the research of various aspects of the mechanism of toxicity of the dioxins, which resulted in over 40 publications on this subject, I have given numerous lectures on this topic, and have served on governmental and non-governmental committees that have reviewed the toxicity of these compounds and their relative risk to human health (see submitted *curriculum vitae*).

Before continuing with the subject of the dioxins, it is pertinent for me to indicate that although I have been requested by the Vietnam Veterans of America, Inc. (VVA) to testify before this committee and will receive reimbursement for travel expenses, I have not received nor will accept additional compensation. My main purpose in being here today is to provide the VVA and this Committee with appropriate scientific information regarding the health effects of dioxin so that an informed decision can be made regarding the possible compensation of veterans exposed to Agent Orange and related herbicides used in Vietnam.

One of the goals of toxicologists working in this area is to characterize the human health risk of exposure to dioxins, and one of the means of approaching this is to identify the health effects elicited and determine the quantitative relationship between the specific exposure and the incidence or severity of the effect. Ideally, information from exposed human populations should be used. In the case of the dioxins, it is clear that some toxic effects such as chloracne have been observed in humans. However,it must be recognized that chloracne may not be, and is unlikely to be the most sensitive indicator of human exposure, but is the one that is most distinct and easily observed. Thus, while effects on more subtle and/or longer term responses such as cancer development and alterations of immune function have been suggested, these have not been **conclusively** demonstrated to occur in humans, and given the limitations of the data d these are unlikely to be conclusively demonstrated in the near future whether or not such effects really exist. Although there are many statistical reasons for this, including the small numbers of individuals in most exposed populations, probably the most important limitations are the lack of data on the amount of exposure and the inability of most studies to measure more sensitive indicators of toxic effects. Therefore, most, if not all, previous studies of humans exposed to dioxins are of limited use for determining quantitative exposure-response relationships and thus notably do not rule out the possibility of adverse effects in individuals of these exposed populations. In recent years the methodology has been developed for the sensitive and accurate measurement of dioxin in human tissues, and future studies of exposed populations may be able to confidently derive a relationship, positive or negative, between some exposure level and a certain toxic effect. To date, I am aware of only two studies to estimate human exposure levels to dioxin or a "dioxin-like" compound (2,3,4,7,8-pentachlorodibenzofuran) and to compare these levels with a toxic effect observed (chloracne). In one case, examination of contaminated food oil consumption data in a Japanese incident and blood values in a Taiwanese poisoning lead to an estimate of between 1.7 and 4.2 micrograms of 2,3,4,7,8-pentachlorodibenzofuran per kilogram body weight that could cause chloracne in a sensitive individual(or an approximate equivalent of 0.85 to 2.1 micrograms of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD, dioxin)/ kilogram) (1). As you will see later in this discussion, these numbers are within the range of doses known to cause chloracne in experimental animals.

Due to the lack of appropriate human data, it is scientifically sound and appropriate that any human health risk assessment of dioxins consider the wealth of information available from animal studies. The use of this information has been the primary basis of risk assessments made on dioxin by state and federal agencies world wide. Although clearly these data are not perfect and a human differs biologically in many ways from experimental animals, these are the only data available for use and are likely to be so for many years to come. From all of these data come some consistent findings that are important for the commitee to consider. These are detailed below. It is first important to note that since these findings are consistent in all experimental mammalian systems yet examined, it is reasonable to deduce that at some exposure level, similar toxic effects are likely to be seen in humans.

1. Although quantitative differences in species sensitivity do exist, dioxin is extremely toxic to all mammalian species yet examined. Notably the approximate body burden shown to cause chloracne in animals ranges from approximately 0.03 micrograms dioxin (TCDD)/kilogram for the rabbit (2) to 9 micrograms/kilogram for monkeys (3). THe body burden levels of dioxin shown to cause chloracne in experimental animals are within the same range of that estimated to cause chloracne in individuals in the Japanese and Taiwanese incidents (to chlorinated dibenzofurans) (1) and German factory workers (to TCDD) (4).
2. Among the consistent effects seen in all mammalian species yet examined include body weight loss and effects on the immune system, including immunosuppression. As little as .002 to 0.1 microgram dioxin/kilogram has been shown to cause significant immune alterations in animals (5). These data indicate that the immune system is one of the most sensitive organ systems to dioxin exposure; in many cases significant alterations have been observed at levels not causing any apparent physical alteration. In addition, dioxin-treated animals have been shown to be more susceptible to viral and bacterial infections, and the ability to combat the malignant growth of tumor cells is compromised. Furthermore, more recent investigations have demonstrated the same degree of sensitivity of certain human cells of the immune system to dioxin exposure as compared to the same cell type from experimental animals (6).
3. Dioxin has been shown to be carcinogenic in all lifetime animal feeding studies yet

performed.

4. The toxic effects of dioxin are mediated through its ability to bind to a specific cellular protein (termed the Ah receptor) and to alter the manner in which DNA is expressed in cells. This receptor protein has been found in a number of human tissues, and experiments using human cells in culture (7) indicate the same degree of sensitivity as animal cells in regard to the ability of dioxin to modulate gene expression.

Again, given these consistent findings in all experimental animals yet examined and the similarity of the sensitivity and mechanism in the limitied number of human tissue studies, it is logical to conclude that similar effects may occur in humans. However, as noted above, for a variety of reasons, the past studies of exposed humans are of limited use. In addition, animal studies have noted that genetic differences may influence the degree of sensitivity towards dioxin. If this same parameter influences human susceptibility, it would be even more difficult for epidemiological studies to discern a relationship between exposure and any particular adverse effect given the vastly diverse genetic nature of a given human population. This would especially be true at exposure levels which may cause subtle, yet significant, toxic effects.

Finally, recent data have been put forth which indicate that some Vietnam veterans who were heavily exposed to Agent Orange have a body burden of dioxin which may be as high as 10-fold greater than "background" levels in a control population (8).

The estimated level of this body burden in these individuals at the time of exposure (approximately 60 ng/kg)(9) is near a level known to cause a number of non-lethal effects such as liver and reproductive alterations and immunosuppression in experimental animals.

In summary, in light of the limited usefulness of studies on exposed human populations, it is scientifically sound and appropriate for any committee reviewing the potential human health risks of the dioxins to consider not only the wealth of available information on experimental animals, but also the data from limited studies on human tissues. The consistent aspects of the experimental animal studies, the species homology of the mechanisms at the molecular level, and the similar sensitivities of human and experimental animal tissues all indicate a toxic significance of these compounds for humans. Furthermore, data suggesting an exposure of some Vietnam veterans to levels of dioxin known to consistently cause adverse health effects in experimental animals are of some concern.

[References and Curriculum Vitae submitted by Dr. Gasiewicz with his statement are being retained in the committee files.]

National Association of Agent Orange Survivors
Post Office Box 822
Oaks, Pennsylvania 19456

TESTIMONY OF

Judy Lewis, Pennsylvania

Mary Barton, Iowa

Judy Pugh, Pennsylvania

Diane Doyle, Arizona

Roslyn Hontz, Pennsylvania

Laurie Rohrer, Illinois

Charlene McPhelin, Pennsylvania

Ann Riley, Alabama

"The right to search for truth implies also a duty; One must not conceal any part of what one has recognized to be true".
Albert Einstein

Testimony of Judy C. Lewis
National Coordinator
National Association of Agent Orange Survivors

IN CONGRESS
HEARINGS BEFORE THE
UNITED STATES HOUSE & SENATE
VETERANS AFFAIRS COMMITTE'S
SENATE BILL S.1787
VIETNAM VETERANS AGENT ORANGE DISABILITY ACT OF 1987

Dear Mr. Chairman,

I am the daugther of a Vietnam Veteran, Leonard Rymarowicz, who died from lung cancer November 18, 1986. My father received a Vietnam Veteran Herbicide Exposure and Health History Questionnaire from the Commonwealth of Pennsylvania Department of Health on September 1984. My father had been experiencing medical problems prior to receiving this questionnaire and finally made an appointment in April 1985 with his family physician. Dad had been troubled by what he thought was severe sinus headaches, nausea, vomiting, bowel trouble, rectal bleeding, arthritis in his arms and legs, numbness in upper legs, and severe back pain. My father was worried most about an unkown mass pressing on his rectal region as he walked. After dad's examination by his family physician, the doctor informed him he did indeed have a large tumor and was very concerned and sent him to the hospital for x-rays, cat scans, blood work and a series of many other medical tests. The diagnosis came back that the tumor the size of a grapefruit was malignant and our nightmare began. Specialists at the Fox - Chase Cancer Center determined that my father had colacogenic carcinoma, which, according to the doctors at the federal Centers for Disease Control, in Atlanta, is a " very, very rare form of cancer ". This cancer spread from the colac tissue throughout my father's body, impervious to all treatment. For the next sixteen months my father received massive treatments of chemotherapy and radiation. What once was a man of self-respect,integrity and whose greatest joys in life were his family and job; he looked forward to everyday, even at the age of sixty-eight. By the age of sixty-nine, my father had gone from a healthy, joyful individual to one with an uncontrolable cancer running rampant in his body, involving his bones, spinal cord and lungs, who had become a parapalegic, hooked to a Foley catheter, ingesting thirty milligrams of morphine every four hours in a fruitless effort to relieve his unbearable pain. This wasted, weak individual's prognosis is very poor. He is not a candidate for further chemotherapy and the treatment plan is for supportive care at home. My father is afraid to go to sleep and keeps the television on all night and when he does sleep it is with his eyes open. He does not want to die and I cry everynight for God to save him, but no one seems to hear our crys for mercy. It is November 18, 1986 and my mother, brothers and sisters are all at dad's side saying our last " I love you ", as dad goes into a deep sleep never to wake again. Our prayers have been answered for dad is no longer suffering and is truly at rest. Even though dad is at rest now, there are two other issues that are not. The first being my younger brother Gary (post Vietnam War baby) who almost died at the ages of two and seven from a mysterious paralysis disease. What kind of a future is Gary going to have since medical studies have indicated, in labratory animals, chromosomal genetic damage is passed down through seven generations. Please don't tell me not to be concerned, because our government has already treated my father as if he were a test rodent. I am only asking for your help in providing a fair and equitable compensation law for Vietnam Veterans and their Survivors; continued studies that target-in on questions of birth defects and long term disabilities among children of Vietnam Veterans; a realistic medical treatment program at VA facilities for any and all illnesses associated with herbicide exposure in Southeast Asia; the concept of the United States Government accepting responsibility for its' envolvement in conducting herbicide spraying operations and the resulting outcome of these operations; any and all studies especially those conducted by independent researchers relative to the agent orange issue. My second concern is the Veterans Administration and who they claim to represent, but don't! After my father's death it took the VA eight months to locate his military and medical records. I wonder if asking Senator Arelen Specter's office to assist us had anything to do with the location of records within four weeks. Then the VA informs me they never received a claim form for Non-Service connected benefits in November 1987. I filled out another claim form which was sent certified mail to the attention of Mr. Robert Carey, Director of the Veterans Aministration Regional Office and Insurance Center in Philadelphia, Pennsylvania and it is now April 1988 and I have heard nothing. How does the Veterans Administration expect claimants to provide evidence in an appeal hearing when: (1) Records are lost (2) Records are destroyed by fire (3) Physician's statement in support of claim is ignored (4) Comrades' eyewitness account statements in support of claim are ignored (5) Copies of military and medical records requested by claimants are never acknowledged (6) Medical testing for dioxin levels for Vietnam Veteran is not available at Veterans Hospitals

(7) Transcripts from appeal hearing are dubbed inaudible on important points of testimony

These unanswered questions along with many others and especially our Governments so-called defoiliation spraying operations in Vietnam (or was it really chemical warfare?) need to be answered.
I can forgive our government but I will never forget what it has taken from me and the look in my father's eyes of total helplessness and with unspoken words the acknowlegement that he was dieing. His death will haunt me the rest of my life, but I will not passively accept the injustice done to my father and thousands of other Vietnam Veterans by our federal government's handling of toxic chemicals in Southeast Asia. In all fairness and justice to our Vietnam Veterans, their children, survivors and concerned citizens of the United States, I would like to request a Congressional investigation of the federal governments handling of this entire issue.

Judy C Lewis

"The right to search for truth implies also a duty; One must not conceal any part of what one has recognized to be true."
Albert Einstein

Form Approved
OMB No. [illegible]

VETERANS ADMINISTRATION

STATEMENT IN SUPPORT OF CLAIM

SOCIAL SECURITY NO.
321-24-7287

VA FILE NO.
C-3101212B

PRIVACY ACT INFORMATION. The information furnished on this form is authorized by existing law (38 U.S.C. 210 (C)(1)) and is considered relevant and necessary to determine entitlement to maximum benefits applied for under the law. The information submitted may be disclosed outside the Veterans Administration only as permitted by law.

FIRST NAME-MIDDLE NAME-LAST NAME OF VETERAN (Type or print)
Leonard Rymarowicz

The following statement is made in connection with a claim for benefits in the case of the above-named veteran:

March 3, 1987

Re: Leonard Rymarowicz

Mr. Rymarowicz was recently under my care for the diagnosis and treatment of bronchogenic carcinoma. This is a gentleman who had been a user of tobacco, but had also been exposed to agent orange while he was in Vietnam. It is my professional opinion that his exposure to agent orange while stationed in Vietnam contributed to the development of his malignancy and hence his death.

(CONTINUE ON REVERSE)

I CERTIFY THAT the foregoing statements are true and correct to the best of my knowledge and belief.

DATE SIGNED
3/2/87

SIGNATURE

ADDRESS
1401 DeKalb St., Norristown, Pa 19401

PENALTY - The law provides severe penalties which include fine or imprisonment, or both, for the willful submission of any statement or

Form Approved
OMB No. "9-R037"

VETERANS ADMINISTRATION **STATEMENT IN SUPPORT OF CLAIM**	SOCIAL SECURITY NO. 321-24-7287	VA FILE NO. c-3101212B

PRIVACY ACT INFORMATION: The information furnished on this form is authorized by existing law (38 U.S.C. 210 (C)(1)) and is considered relevant and necessary to determine entitlement to maximum benefits applied for under the law. The information submitted may be disclosed outside the Veterans Administration only as permitted by law.

FIRST NAME - MIDDLE NAME - LAST NAME OF VETERAN (Type or print)
Leonard Rymarowicz

The following statement is made in connection with a claim for benefits in the case of the above-named veteran:

I hereby certify that this information is true and correct to the best of my knowledge and belief.

I, Charles R. Kariainen served in South Vietnam from the date April 10 1967 to April 10, 1968. I served with the 35th Engr Battalion (Combat) 18th Engr. Bde.

I have observed light helicopters spraying defoliant around our base perimetter and other unit positions in the year 1967. (LZ English and LZ Hammond)

I don't know what units the helicopters were attached to that did the spraying of A. Orange but the spraying did the job it was desinged for.

The officers in my company did not know or did nothing to take preventive measures to protect the health of the men under their command. Whom is at fault, the chemical company or the U.S. Govt.

(CONTINUE ON REVERSE)

I CERTIFY THAT the foregoing statements are true and correct to the best of my knowledge and belief.

DATE SIGNED: 6-8-87"
SIGNATURE: Charles R. Kariainen
ADDRESS: E6344 Wood Lane Bessemer Mich. 49911

WARNING. It is illegal to alter this copy or to duplicate by photostat or photograph.

H105 112 REV 11-85
(FEE FOR THIS
CERTIFICATE $2.00)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH-VITAL RECORDS

No. 67277

LOCAL REGISTRAR'S CERTIFICATION OF DEATH

Registered No. ____

Full Name of Deceased: Leonard (First) ____ (Middle) Rymarowicz (Last)

Residence: 21 Merion Avenue (Number, Street) West Conshohocken (City or Town) Montgomery (County) Pa. (State)

Place of Death: Montgomery (County) Norristown (City, Borough or Township) Pennsylvania

Sex: Male Date of Death: 11-18-86 Race: White

Date of Birth: 6-4-1918 Birthplace: West Conshohocken, Pa. Marital Status: Married

Social Security No.: 321-24-2287 Occupation: Maintenance Supervisor Veteran's Serial No.: RA 6947016

MEDICAL CERTIFICATE
Part I. Death was caused by:

		Interval Between Onset and Death
Immediate Cause (a)	Metastatic Oat Cell Carcinoma	16 mos.
Due To (b)		
Due To (c)		

PART II. OTHER SIGNIFICANT CONDITIONS contributing to death but not related to the immediate cause given in Part I (a) ____

Accident, Suicide or Homicide ____ How did injury occur ____

Name and Title of Person Who Certified Cause of Death (M.D., D.O., Coroner, M.E.): C. Sharer, D.O.

Address: 1651 Markley St. (Street) - Norristown, Pa. (City)

This is to certify that the information here given is correctly copied from an original certificate of death duly filed with me as Local Registrar. The original certificate will be forwarded to the State Vital Records Office for permanent filing.

Thomas J. Ruggiero UA (Local Registrar of Vital Records) 46-425 (District No.)

217 West Elm St. (Street Address) - Conshohocken (City, Borough, Township)

November 19, 1986 (Date Received by Local Registrar)

November 20, 1986 (Date of Issue of This Certification)

National Association of Agent Orange Survivors
Post Office Box 822
Oaks, Pennsylvania 19456

March 22, 1988

Honorable Senator Alan Cranston
112 Hart Senate Building
Washington, D.C. 20510

Honorable Senator Cranston:

Enclosed, please find my testimony regarding a sumary of what has happened to my husband. Please take the time to carefully read this sumary, as actual documentation can also be provided for each test which was performed on my husbands body after his death.

Thanking you kindly in advance for reviewing this tragic Agent Orange story.

Sincerely,

Mary Barton

Mary Barton
National Fundraising Director

"*The right to* search for truth implies also a duty; One must not conceal any part of what one has recognized to be true".

On October 7, 1986, we were told that Wayne had cancer, which was already in the fourth stage. We were also told at that time, that with out any treatment at all we were looking at perhaps six months. The Cancer was already in the lining of the lung, throughout the bones, and in the adrenal glands. But the doctors were optimistic, telling us that they were planning to use the strongest chemotherapy available in the U.S. They also told us that 85 percent of the population of the U.S. was unable to tolerate a dosage of this strength, and of the 15 percent that were able to tolerate it they were seeing a 70 percent remission. The appropriate tests had to be made to see if he could tolerate the massive dosages of chemotherapy which the heart tests and kidney tests and other tests showed that he would be able to tolerate. Instead of staying the expected three days for the treatment, he ended up having to stay 10 days because of the different reactions he had from the massive treatment. When he came home, he was very anxious to return to work, only to find that the next nine days he worked, was the last days he was ever able to work again. Over the period of the next two weeks at home after his first treatment, he lost all of his hair, became gravely ill at different times, ran high fevers, and started loosing a lot of weight. After all of these reactions, it was then time for his second treatment, but this treatment was very different than the first treatment because he violently reacted to the chemicals, and for a period of 2 or 3 days he was having very adverse reactions from not even knowing me or where he was, and they finally had to stop some of the chemicals they were giving him because of the reactions. Once the chemicals were stopped he returned to normal and of course did not remember anything that had happened during those previous days. His Oncology Doctor, as well as the Heart and Lung Specialist continually called over the U.S. to see what new techniques of medicine could be tried.

From October 7, 1986, until January 20, 1987, which was only a period of three months, he had to be hospitalized several times, because of high fevers, infections, and various other treatments they would give him. He had lost over 40 pounds during those three months. He was extremely ill all of the time, and was hospitalized on several occasions for biopsies of various tumors which had started erupting almost over night. On one occasion, he had five tumors erupt from a Friday night through a Monday morning.

On January 20, 1987, I took Wayne back to the hospital, which turned out to be his final trip to the hospital, because the next 72 days of his life, he lived in pure torture, not only for Wayne, but for everyone concerned. We saw him going through extreme pain, extreme loss of weight, tumors still erupting over night. They soon had to change him over to a Clinitron bed, because it was a floatation mattress, and there was such threat of bone breakage on the other mattresses they had tried. This floatation mattress eased the pain for such a short time, but that was the extent of the beds they could use, because they had tried the air mattress, the water mattress, and everything else they could think of to try to make him as comfortable as possible. Every nurse, that treated him, and every Doctor that treated him, kept telling us that they had not seen anything like what Wayne was going through before, except perhaps on one other occasion. They started talking about Wayne's exposure to Agent Orange at this time, because of the adverse reactions, and the unresponsive, and aggressive nature his disease was taking.

Most of the 72 days he was being fed through the veins, as the smell of food would also cause adverse reactions. He continually had a stomach pump going, because of bleeding internally. At one point he had to be rushed to the emergency room because he had developed a nose bleed that was uncontrolable.

To be bathed, caused much intense pain, and could only be accomplished with the aid of usually four nurses, and to turn him, took seven to eight nurses, and it was not because of his size, but because of the threat of bone breakage.

Wayne's doctors spoke on television, and also wrote various letters to 60 Minutes Television Program, because they were so concerned about this patient which they were trying virtually everything possible, and yet still witnessing reactions they had never seen before, and simply were making the public aware of their concerns. Wayne finally asked his doctor to please make sure that after this final battle was over to find out for sure if indeed Agent Orange was responsible, and perhaps this would be able to help other Veterans. He also made me promise that I would see that his wishes were fullfilled, and I gave him my promise.

Over the next several weeks that he lived, we were all so helpless, the look of love in Wayne's eyes was the only thing that resembled the husband and father we loved so dearly, because by now he had lost so very much weight, the pain had invaded every part of his body, and he had been on IV morphine drip for many weeks which gradually had to be continually turned up because of the intense pain. I could not even touch Wayne any longer, because of the immense pain it caused.

Finally the last few weeks he lived, he slept most of the time, because the morphine, had to be turned up so high to control the pain. He had much difficulty breathing, and because of the morphine, much of the time those last few weeks, Wayne was reliving over and over his tour of duty in Vietnam, shouting out loud many times to fellow comrads about in coming mortars. One day his mother and I were in his room and he was shouting so loudly to fellow comrads that we had to finally close the door.

At 4:53 A.M. on April 2, 1987, God took him home, away from this horrible pain. After his death, his doctor had his body sent to the Veterans Hospital in Iowa City, Iowa for an autopsy to carry out his patient's desire to help other veterans.

In June, I received the autopsy report back, and it showed that the dreadful disease had pratically consumed every organ, and over 60 percent of all the bones, and the adipose tissue sample which was sent to Nebraska, for Dr. Michael Gross to do a dioxin analysis on, did indeed show that he had 12 parts per trillion of 2,3,7,8, TCDD - dioxin in his body.

Wayne did not farm, nor was he ever ill in the 23 years that we were married. The Veterans Hospital, Chief of Staff, has acknowledged the fact that my husband did die with an elevated level of dioxin, but he states in various newspapers that he feels my husband got his high level of dioxin from living in the farming community. We have two adopted children, of which I have never brought up the fact of how many miscarriages we have gone through, before we finally adopted our two children. Once I received the autopsy report back, and it states right in the report, that "it raises the question whether this was injested during Military service, or was it just inviornmental living in the United States" My primary concern, is the fact that my husband did die with an elevated level of dioxin in his body, and he did not farm, and did not become exposed to high levels of dioxin in his work, I guess the only logical answer I have is that knowing how heavily exposed he was to Agent Orange I plead for your help in resolving this matter as far as other fellow veterans of my husband's are concerned.

Please take into consideration, what has happened, in this particular case, and prevent this from happening to any other Veteran, by listening to the rest of this tragic story on May 12, 1988, as a witness in behalf of the many many thousands of Vietnam Veterans throughout the United States that have virtually begged to have a dioxin analysis done, and all been denied. Please allow me to give my testimony, because I will not be speaking from mere speculation, or happenstance, or guessing that perhaps Agent Orange might have played a part in my 43 year old husband's illness and death, but I will have actual documentation, of exactly how many times my husband was exposed in just an at random 90 day picking, during his tour of duty in Vietnam. Please allow my testimony to be heard as a representative for the many thousands of Vietnam Veterans.

Thanking you very kindly for your time in reading this story.

75[illegible]0-CO-6[illegible]-41.

MEDICAL RECORD | **AUTOPSY PROTOCOL**

DATE AND HOUR DIED: April 2, 1987 4:53 a A.M. P.M.

DATE AND HOUR AUTOPSY PERFORMED: April 2, 1987 4:00 p A.M. P.M.

CHECK ONE:

FULL AUTOPSY	HEAD ONLY	TRUNK ONLY
XX		

PROSECTOR: Thuy-Lieu Vo, M.D.

ASSISTANT

CLINICAL DIAGNOSES (Including operations)

PATHOLOGICAL DIAGNOSES

1. Adenocarcinoma, moderately to poorly differentiated, right lung with metastases to hilar lymph nodes, paraaortic lymph nodes, ribs, vertebrae, scapulae (by history), diaphragm, liver, pancreas, kidneys, adrenals, omentum, mesenteries, bowel wall, bladder, subcutaneous fat.
2. Septicemia (Klebsiella Pneumoniae).
3. Pneumonia, acute, focal, bilateral.

APPROVED - SIGNATURE: THUY-LIEU VO, M.D. TLVo

DIAGNOSES APPROVED BY: T. KENT, M.D. TKent R.T. COOK, M.D. RTCook

DATE:

MILITARY ORGANIZATION (When required)	AGE	SEX	RACE	IDENTIFICATION NO.	AUTOPSY NO.
Civilian	43	male	caucasian		AV87-33

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle; grade, rank; rate; hospital or medical facility)

BARTON, WAYNE
DOB: 2/14/44
VAMC, IOWA CITY, IOWA

DR: 6/5/87
DT: 6/5/87 ac

REGISTER NO.: 482-52-1560

WARD NO.: outside h

AUTOPSY PROTOCOL
Standard Form 503 (Rev. 2-79)
Prescribed by GSA/ICMR
FIRMR (41 CFR) 201-45-505
503-109

☆ U.S. GOVERNMENT PRINTING OFFICE [illegible]

DISCUSSION OF AUTOPSY FINDINGS & CLINICAL PATHOLOGIC CORRELATION

This 42 year old man, who was a heavy smoker, was diagnosed at an outside hospital in the fall of 1986 as having undifferentiated carcinoma of the lung with multiple metastases. His disease progressed in spite of chemotherapy and radiation treatment. He was brought to VAH after death for autopsy.

At autopsy the 3.0 cm right hilar carcinoma invaded bronchi and was the source of widespread metastases. All the other lesions had the appearance of metastases.

The diagnosis of adenocarcinoma of the lung with widespread metastases in this patient is unequivocal. Many studies have been done on the topic of lung cancer and smoking, and have shown a strong positive relationship between the two (1-4).

According to the history available to us, this patient had a 40 to 60 pack year smoking history of cigarette smoking, placing him at considerably increased risk of carcinoma of the lung. His course after diagnosis was rapid, but as is well known the biology of malignant neoplasms is quite variable and the aggressiveness of a specific neoplasm cannot be related to the inciting agent. Thus, the rapidity of this patient's course and the fatal outcome do not appear exceptional in terms of the general spectrum of tumors of the lungs.

Causes of death: Widely metastatic carcinoma of the lung and septicemia.

Note on Agent orange:
The patient reported a history of agent orange exposure. Postmortem studies of the abdominal fat showed 12 parts/trillion of one dioxin isomer. Agent orange is a 50:50 mixture of butyl esters of 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (2,4,5-T). Both 2,4-D and 2,4,5-T have been used extensively in the United States for more than 30 years as agricultural herbicides in the control of broad- leaf plants and to clear unwanted vegetation along rights-of-way. During its chemical synthesis, 2,4,5-T is contaminated by an unwanted by-product, 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD). Although TCDD is only one of 75 chlorodioxins, this isomer is considered to be the most toxic. Agent orange was used in Vietnam by U.S. military for defoliation, crop destruction, and to clear vegetation around military installations. In addition to the TCDD containing agents, the military was also spraying garden insecticides. Thus, it is possible that many servicemen who were sprayed only with insecticides may believe they have come into contact with the herbicide Agent orange. Once ingestion occurs, TCDD stores in various organs; studies performed on autopsies of known exposed individuals, show that TCDD levels in the blood are one tenth the levels of TCDD in liver tissue and one hundredth the level in adipose tissue. Adipose tissue has the highest

concentration. The half life of TCDD appears to be very long and one can detect the level many years after exposure. In the United States, the TCDD levels in adipose tissue of some people, who lived in contaminated areas, or some farmers have reached levels of hundreds of parts/trillion. The 12 parts/trillion TCDD level in this patient's adipose tissue is somewhat hard to interpret. It raises the question whether the substance was ingested during military duty or was it just environmental exposure while living in the United States. Questions have been raised about any relationships of this agent to birth defects and cancers. Up to date, there have been many retrospective studies done on the subject, however, there are no studies to support nor demonstrate a relationship between dioxin and birth defects or sarcoma/carcinoma, to the best of our knowledge.

References:
1. Ca-A Cancer Journal for Clinician, American Cancer Society, 1983 March-April, 33 (2), 74-86.

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3. Robbins et al Pathologic Basis of Disease, 3rd edition, 750-755.

4. Petersdorf et al, Harrison's Principles of Internal Medicine, 10th edition, 1572-1579.

5. Dan B., "Vietnam and Birth Defect", JAMA, 1982, August, 252 (7), 936-37.

6. Young A., "Determination and Measurement of Human Exposure to the Dibenzo-p-Dioxins", Bullet. Environ. Contam. Toxicol., 1984, 33, 702-09.

7. Silbergeld E. et al, "Experimental and Clinical Studies on the Reproductive Toxicology of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin", Am. Indust. Med. 1987, 11, 131-44.

8. Henderson J. et al, "Occupation-related Male Infertility: A Review", Clin.Reprod. Infert., 1986, 4, 87-106.

9. Greenwald P. et al, "Sarcoma of Soft Tissues after Vietnam Service", JNCI, 1984, 73, 1107-1109.

B.S. AJAIKUMAR, MD

ROHINI REGANTI, MD

ONCOLOGY SERVICES, INC PC
620 NORTH EIGHTH STREET
BURLINGTON, IOWA 52601
319-753-1220

January 29, 1988

TO WHOM IT MAY CONCERN:

This letter is being written in Dr. B.S. Ajaikumar's absence regarding Mr. Wayne Barton, who was a patient in this office, who was diagnosed with carcinoma of the lung with metastatic disease. Mr. Barton upon diagnosis of his illness, and throughout the treatment of his disease, did have a very good morale, and had a very positive attitude concerning his treatment and disease. His disease was very aggressive in nature and did not respond to chemotherapy, nor radiation therapy, and subsequently Mr. Barton did expire. He did indicate that upon his death, he did want any tests to be done, which might connect his aggressive lung carcinoma to his exposure to Agent Orange, while in Viet Nam.

The patient was treated by Dr. Ajaikumar regarding his cancer, and also seen by me in his absence. It is our opinion that he did experience a very aggressive type of carcinoma which was resistent to all forms of therapy.

At this time, I do not have an access to tests done in Iowa City from his autopsy. Dr. Ajaikumar will be available after March 15, 1988.

Sincerely,

RReganti

Rohini Reganti, M.D.

AB/sep

Radiation Therapy and Oncology
602 North Third Street
Burlington, Iowa 52601
319/753-3355

March 9, 1987

Mr. Ed Bradley
60 Minutes - CBS Television
51 West 52nd Street
New York, New York 10019

Dear Mr. Bradley;

I am a radiation therapist and oncologist practicing in Burlington, Iowa. I would like to bring to your attention a patient that I am treating at present who is a Vietnam veteran and had exposure to Agent Orange. He is 42-years-old and at present he has an advanced cancer of the lung and he has not responded to any type of treatments. He had exposure to the Agent Orange about 18 years ago. In this patient's case the disease has been aggressive and has not responded to any form of chemotherapy or radiation therapy treatments. This kind of non-responsiveness is unusual in somebody with cancer of the lung if it is just related to smoking only. I do believe that in this patient, Agent Orange has played a significant role. The patient's name is Mr. Wayne Barton and he was a very healthy individual before the disease struck him in October of 1986. Since then he has had a very painful and progressive disease. This has had a very devastating effect on the patient's family, both emotionally and financially. It is very sad indeed that the government is unable to do anything to help this Vietnam veteran.

This is the second patient that we have had in the last four years, with this type of disease. We had a patient that was 34-years-old, who had a similar course of disease and expired.

I sincerely feel that the government should recognize the fact that their Agent Orange could be a cause of cancer and provide the necessary help to the patients and their families. I do know that this matter has been investigated before. I hope though that you will further investigate this so people who are affected by this deadly disease can be helped.

With regards, yours truly,

P. S. Araikumar, M.D.

BMC Burlington Medical Center
602 N. THIRD ST. / BURLINGTON, IA 52601 / (319) 753-3011

March 12, 1987

TO WHOM IT MAY CONCERN:

Re: Wayne Barton

I have the privilege to introduce a gentleman who is 42 years old, who has advanced carcinoma of the lung. Unfortunately, the gentleman has served in the Vietnam war, where he was exposed to Agent Orange. Mr. Barton had been a very healthy person and subsequently was seen by me in October, 1986, when he was diagnosed to have carcinoma of the lung, a very aggressive tumor, manifested in the form of bone metastasis attesting to the aggressive nature of the tumor. The patient had been a smoker, but in my experience and the literature I have reviewed, usually cancers of the lung subsequently going to the bones have responded very well to chemotherapy as well as radiation therapy. With my limited experience with Agent Orange, as a lung specialist I feel that this gentleman has suffered a significant amount in terms of his pain and agony from the tumor, as well as the effect of the cancer itself on the patient. I believe, with my experience, that he would never make it from this cancer.

This has had a very bad effect on the patient's family financially, as well as emotionally. I wish the government would do anything to help these people who have served this country. I have dealt with the family closely in the last four to five months, and feel that it is a very sad situation for the wife and children to see their husband and father dying; in spite of aggressive treatment with chemotherapy and radiation, he has not responded even a little bit. Every time we turn around, we see a new place where the tumor is coming out, in terms of skin and the brain. I hope somebody is sensitive enough regarding the people who have served their country, to look into this matter and see if something could be done for the families of these people.

If anybody has any questions regarding this, I would be willing to answer them.

Very truly yours,

Shan Bedi, M.D.

mlm

Acute Care / Skilled Nursing Unit / Klein Unit Intermediate Care Facility / Home Health Care
Rehabilitation Services / Day Surgery / Riverview Rehabilitation Center for Alcohol and Drug Abuse

B S Ajaikumar, MD, PC
Rohini Regenti, MD

Radiation Therapy and Oncology
602 North Third Street
Burlington, Iowa 52601
319/753-3366

March 24, 1987

To Whom it May Concern:

Re: Wayne Barton

Mr. Bartin is a 42 year old gentleman with metastatic carcinoma, poorly differentiated adenocarcinoma. His primary site of cancer is in the lung with evidence of metastases to the bone and meninges. Diagnosis was made October 1986. At that time he had excruciating pain in the backbone and in the right rib area. He was started on the most aggressive form of chemotherapy which included Adriamycin, Cisplatinum, Cytoxan, 5FU combination. Subsequently he has been treated with several combinations with no significant response. The patient has not had any response to the chemotherapy or any significant response to radiation as a palliative measure. The disease has been very aggressive in the bone and also in the meninges. In looking back in Mr. Barton's history, there is a history of smoking as well as exposure to Agent Orange in Viet Nam. In my opinion there is a trend in the patients who were exposed to Agent Orange in that the cancer they develop is very resistant to any form of therapy. When people have cancer of the lung related to smoking only, at least initially they have a fairly good response to the therapy. However when they have additional factor like exposure to Agent Orange it is possible that the disease becomes very resistant to any form of therapy. Unfortunately from all available data which has been collected in different centers, including the Center for Disease Control in Atlanta, there is no definite study done on lung cancer as such in relationship with Agent Orange. In my opinion it is possible that Agent Orange exposure has made the disease aggressive and resistant to therapy. I do believe Mr. Barton and his family need all the help in this critical time, both emotionally and financially. I hope that help can be provided by various agencies. Mr. Barton has done his service to the country by going and fighting in Viet Nam and I do believe he deserves recognition and help from the concerned parties. Thank you.

With highest regards,

B. S. Ajaikumar, M.D.

BSA/nh

cc.

Addendum to Testimony of Mary Barton

I am writing this addendum to my testimony since I believe it is important to have included in the offical records the callousness shown by the Veterans Administration and in particular by Dr. Lawrence Hobson, Director of the Veterans Administration's Agent Orange Projects Office. This addendum will also serve to document Dr. Hobson's admission that the VA made a mistake in testing my husband for the dioxin level in his body.

On April 15, 1988, at a meeting of the Veterans Administration Advisory Committee on Health Related Effects of Herbicides, Mr. Wayne P. Wilson, Executive Director of the New Jersey Commission on Agent Orange, asked Dr. Michael Gough, Chairman of the advisory committee, for a statement on VA policy regarding actual dioxin analysis on Vietnam Veterans citing a particular reference to the analysis performed on Wayne Barton of Iowa, a deceased veteran. Wayne Barton, as you know by now, was my husband.

The reply to Mr. Wilson's question came from Dr. Hobson, who in effect said that the VA does not have a policy on actual analysis and that "the analysis done on the veteran in Iowa was an error, a mistake".

Mr. Wilson and I are of the opinion that this statement by Dr. Hobson admits that the government is fully aware of the effects of dioxin on exposed veterans and that my husband's case is one that the government can no longer simply dismiss for lack of proof, since their analysis revealed high levels of dioxin. Indeed, Dr. Hobson may hold the conviction that the VA was mistaken in testing Wayne Barton, since without this proof the government could continue to deny the deleterious effects of dioxin exposure.

I might also add that Senator Harkin's office, in Iowa, investigated the VA's claim that my husband's dioxin level was due to environmental exposure where he worked and lived, rather than from exposure in Vietnam. The Senator's office evaluated the cancer rates for the areas where my husband lived and worked and concluded that the VA's claims were groundless.

I am dismayed, although by this time, I shouldn't be, by the callousness and total lack of compassion shown by the Veterans Administration and Dr. Hobson in making the statements they did to Mr. Wilson without having the courtesy to communicate these statements to me personally.

Rather than healing the wounds of veterans and their survivors the VA seems intent on pouring salt on these wounds. I have to wonder, with all that is currently general knowledge about the government's mishandling of toxic chemicals and the general lack of concern for our soilders well being both in Korea and Vietnam, how the government might ever expect to raise a dedicated fighting force should a legitmate need arise.

TESTIMONY OF JUDITH J. PUGH
REGIONAL COORDINATOR
NATIONAL ASSOCIATION OF AGENT ORANGE SURVIVORS

IN CONGRESS

HEARINGS BEFORE THE
UNITED STATES HOUSE AND SENATE
VETERAN'S AFFAIRS COMMITTEE'S
SENATE BILL S. 1787
VIET NAM VETERANS AGENT ORANGE
DISABILITY ACT OF 1987

Dear Mr. Chairman:

It is with faith in our system of mercy and justice that I write my testimony for my deceased husband, Robert Lawrence Pugh.

Being a young soldier in 1968, Robert, at nineteen years of age, hated what he was doing and realized the situation was not what he had anticipated. Sometime during his tour in Nam he was introduced to heroine and left there after his twelve-months' tour of duty as a heroine addict. This addiction plagued him for fifteen years.

While serving in Viet Nam, he drove a supply truck on U.S. Route 1. He was stationed in the Tay Ninh Province and was based in Binh Wah. He drove these trucks through jungles that were being heavily sprayed with dioxin and other toxic herbicides. He stated to me once that he remembered that the spraying was going on all the time.

He returned to the United States an ignoble warrior with a monkey on his back. The Veteran Rehabilitation programs were not available for detoxification and so he was released from the Service to make it the best way he could.

Needless to say, his addiction increased and this led to a life of crime in order to feed his habit. He was eventually caught and jailed and spent the next fifteen years of his young life in either a drug program, shooting dope, using methadone, or serving time in jail.

Six years' ago Robert was arrested for the last time. He was sentenced to four years in State Penitentiary, where I first met him. I was working as the Nursing Administrator of the Medical Department in the jail.

I saw him often as I worked throughout the jail. And I saw the change in him. It was during the five months that he was locked up for twenty-three hours a day in a single cell that Robert realized he would die if he kept on this way. He asked for help from God and received it. For the remaining three years of his sentence he worked very hard for his parole. He was sober and Saved and we became friends.

On February 14, 1984 we were married while he was still serving his sentence. He made parole and came home in July 1985.

Soon thereafter he began experiencing pain in his back. We went to five different doctors to find out why. He was in so much pain he could not lie down at night but kneeled at the bed and leaned on it. None of the doctors ordered any tests. He had told all of them of his previous heroine addition, but they all prescribed a narcotic to control the pain.

Finally after about a year and the pain had gotten so bad and he had lost fifty pounds, we went to Doctor No. 6 and he ran a Cat Scan. This revealed a "small" tumor on his left adrenal gland. Robert had a very unhappy 39th birthday on August 27, 1987. The pain was unbearable. On August 31st he had an exploratory laparatomy to excise this "small" tumor. The surgeon was aghast. The "small" tumor had grown into the muscle of his back, which is why he could not lie down. It had metastasized to three areas around his aorta and encircled it. His "small" tumor was inoperable. The cells were virulent and did not respond to heavy chemotherapy nor to radiation. His weight dropped to 100 pounds, he lost his hair and during the last three weeks he was psychotic. He died November 21, 1987 on massive doses of morphine.

To say that Viet Nam impacted on this man's life is making a mild statement. He was able to salvage five years out of his life through his belief in God-in his sobriety. He actually only "lived" two years after being released from prison. And now he is gone along, with all our dreams of a future together.

Metastatic carcinoma of the adrenal gland is extremely rare. Thirty-nine-year-old men do not generally die from this. This man had been exposed for twelve months of his life to dioxin. His immune system had been depressed from the stress of Nam and then the addiction to drugs.

I mercifully implore you to consider the passage of Bill 1787, which will provide a compensation plan for Viet Nam veterans and their survivors who have all been affected by Agent Orange.

Judith J. Pugh

Judith J. Pugh

Dianne Doyle
6726 East Holly Street
Scottsdale, Arizona 85257

April 28, 1988

Judy Lewis, National Coordinator
National Association of Agent Orange Survivors
P. O. Box 822
Oaks, Pennsylvania 19456

Dear Judy,

I was given your name by the New Jersey Agent Orange Commission, specifically by Victoria McGuire there. She said that it would be to my advantage to contact you, as you have a number of resources for the survivors of Agent Orange. I am not even sure if I am an Agent Orange survivor, as no one has yet told me if I am to be considered for the settlement. But I have submitted my claim on behalf of my son, who was born with a malignant tumor of the nasopharynx, and I was told by his surgeon and every doctor who ever looked at the biopsy slides, that it was highly unusual for a baby to be born with this kind of tumor. It was only recently that I was told about the possibility of Agent Orange being responsible, and that only came from the local Vet Center here in Phoenix.

Since my husband is dead (self-inflicted gunshot wound to the head 1½ years after returning from Vietnam), and since I was 3 months pregnant at the time, there was never any reason for me to suspect that it was anything but more senseless tragedy. It took the suggestion of a veteran doing counseling to put me in touch with the Agent Orange organization. I had spent the first 5 years of my son's life in and out of hospitals (with him) working several jobs in order to pay for the $40,000+ in medical bills, so my investigating probable causes then was not a possibility. So, I hate to say it, but I am very ignorant about Agent Orange. I can tell you anything you want to know about nasopharynx tumors, but on the topic of Agent Orange, I am completely uneducated. Is there a general, all-purpose educator that I could either be put in touch with locally, or a book that would pretty well sum up what you feel it would be wise for me to know?

I don't know if you send material to me through the mail or whether you simply send a letter telling me where to go to get what I need. So in the event that you send things through the mail, I am sending 4 25¢ stamps to cover postage. Should you not use all of them, please keep them for whatever you would need them for. Yours surely is a worthy and much-needed organization, and no doubt in need of every minor contribution it can get its hands on. Should it come to more than the $1 in postage, I will send the additional stamps when I see how many more are needed.

Thank you for the work you are doing and for allowing your name and organization to be given out as reference points for help.

Sincerely,

Dianne Doyle

TESTIMONY OF ROSLYN HONTZ
NATIONAL EXECUTIVE SECERTARY
NATIONAL ASSOCIATION OF AGENT ORANGE SURVIVORS

IN CONGRESS
HEARINGS BEFORE THE
UNITED STATES HOUSE AND SENATE
VETERANS AFFAIRS COMMITTEE'S
SENATE BILL S. 1787
VIETNAM VETERANS AGENT ORANGE DISABILTY ACT OF 1987

I am not a survivor as are the other women who have already testified before me; my husband is living, living with Non-hogkins lymphoma. He is 39 years old.

My husband joined the Marine Corps when he was 17 years old. At 18 he was sent to Vietnam; he received two Purple Hearts during his tour of duty 1967-68.

The only way to decribe what it is like to live with tis disease is to compare it to walking through a mine field. Count every day in your life as a step never knowing when a mine may go off. You might have a small explosion and suffer for awhile but you're not dead you go into remission and carfully keep walking, hoping it will be a long time before there is another explosion. Knowing that there will be a day that you will step on the one that there is no control of and no getting away from.

Imagine knowing you may not see your children graduate; having to plan for your families future without you, talking about things most people don't even think of mentioning until they are older. Imagine me watching him try to do everything he ever promised me for our lifetime today, for fear tommorrow will be to late.

Because of this illness he stopped driving truck over the road where he was making excess of $35,000 a year, he had to take a lesser paying job to be able to be home for blood tests, doctor appointments and other tests necessary for the doctor to properly try to treat the disease.The last treatment was 17 months of Chemo-therapy, the medication alone cost $164.00 a month. He is covered on my insurance where I am employed but what about the Veteran who doesn't have enough coverage? Treatment for this disease is very expensive.

"Why not go the V.A." you might ask? Have you ever gone to a V.A. clinic? You wait for them to find your records and hope they are really yours, you go to another room and wait, you are shuffled around until you finally see a "doctor" but you are not sure he is a doctor. When my husband went for his Agent Orange Exam they wanted to draw blood but could not because when they made the appointment they forgot to tell him not to eat, they told him to come back another day. The "doctor" he saw was a crude man who referred to his personal physicians as "high-falutin' specialists". My husband left the V.A. clinic angry for the treatment of himself and the other veterans that were there vowing never to go there again. Saying "the dogs get better treatment at the dog pound!" Would you trust your life to these people?

The disease causes enough mental stress by itself which should not be complicated by worries about medical bills, or hassles from the V.A..

The presomption that dioxin or other herbicides used in Vietnam has been delayed long enough. The passing of this bill will be the beginning of the end of a battle these men and women have been fighting since Vietnam.

A VET'S WIFE'S TESTIMONY

As a Vietnam veteran's wife I have had to struggle with the unknown. Now Rich and I struggle with the diagnosis of toxic chemical syndrome due to exposure to Agent Orange.

Rich and I married in 1971, 2 years after his return from Nam. During the 2nd year of our marriage Rich began having health problems; irritability, depression and sleepless nights. He had difficulty going to work and did not want to socialize. During the next few years he continued struggling with these problems taking prescribed tranquilizers and anti-depressants, not knowing what was causing all his problems.

During 1979 these problems intensified with a 40 lb. weight loss. He would eat huge amounts of food but still kept losing weight. Along with the weight loss, he developed skin rashses, throbbing head, inability to concentrate for long periods of time, and had pain so intense that he had to crawl to the bathroom. Because of the unknown, he became frightened "What was wrong with him, the doctors are beginning to think he's making these problems up as they could not diagnose the problems". The tension of the unknown added to his physical problems, resulted in depression and rages, landed him in a mental hospital. The doctors had Rich so doped up I had to request they but back his medication. It was frightening to see him in this condition - this was not my husband!

As a wife, being healthy and seeing the restrictions his health and the unknown were placing on our marriage nearly broke it apart.

Rich could and cannot work. I am the sole breadwinner trying to keep the bills paid along with his medical expenses. We sold our car and some household items to meet his medical bills.

I was sick and tired of my life being restricted because of his health. I got to the point I began shutting him out of my life as I was tired of coming home from work worrying about him, sensing his depression. Rich had shut himself off from society to avoid the hurt of feeling uncared for or not being understood. This was his protection from society. For years his life became "four walls" and I couldn't stand it much longer.

We now know the unknown but struggle with his irreversible health problems and the frustration of not being compensated for serving his country. Because as a result of serving his country he will not only spend the remainder of his life suffering physically but also emotionally feeling his government could care less about him.

While serving in Vietnam it was a day to day struggle to avoid death by the enemy. However, at the same time our men did not realize that the chemicals sprayed by our government were toxic and harmful which would result in health problems and for some vets death.

Why is the government afraid of acknowledging those veterans who were exposed to the chemicals and now are suffering? The choice of going to Vietnam was not voluntary by most vets but was compulsory by the government. The government mandates you serve during an "undeclared war" but will they reciprocate for those who now suffer?!

After Rich was diagnosed toxic chemical syndrome due to exposure to Agent Orange and other herbicides we began doing research. The more we read and spoke with others the more his health problems and exposure to Agent Orange made sense. We did not realize how many vets and their families are suffering.

My heart goes out to the Vietnam vet and his family!!

Respectfully,

Laurie Rohrer
513 Hartford #6 So.
Aurora, IL 60506

April 20, 1988

Dear Mr. Chairman,

My husband, Charles McPheli came home from Viet Nam on August 25, 1969. He was a corporal in the Marine Corp. We were married on February 20, 1971 and have five children.

Chalie wrote to me about Agent Orange, while in Viet Nam. He talked about how beautiful the foliage was before they would spray, but they had a difficult time cutting through it. He told me how barren it was after they sprayed agent orange, and he couldn't believe how quickly it killed everything. He also wrote about the weather, how hot it was. Most of his pictures are him and his friends without shirts.

Chalie had a mole on his upper back on the left side. In February, 1984 the mole turned black. He had it removed at the Police & Fire Medical Clinic in Philadelphia. The biopsy showed it was malignant Melanoma.

He entered Rolling Hill Hospital to have a wide incision. Every thing was fine for almost two years. He started with lower back pain in November. He was admitted to Rolling Hill Hospital on February 4, 1986. They removed his spleen and part of his bowel. About a week later they had to insert a tube through his lower back to drain the blood and fluids. The tube was later changed to different spot. When they finally removed the tube, the tumor continued to bleed through the skin. My husband died on June 29, 1986 at Fox Chase Cancer Center.

About a month before Chalie died, Dr. Masterangelo from Jefferson Hospital, who is a Melanoma Specialist, came to see Chalie. He prescribed an aggressive Chemotherapy that might give him a chance. He asked Chalie if he was in Viet Nam and where

Later I asked Dr Masterangelo, if he thought his cancer was caused by Agent Orange. He said, yes

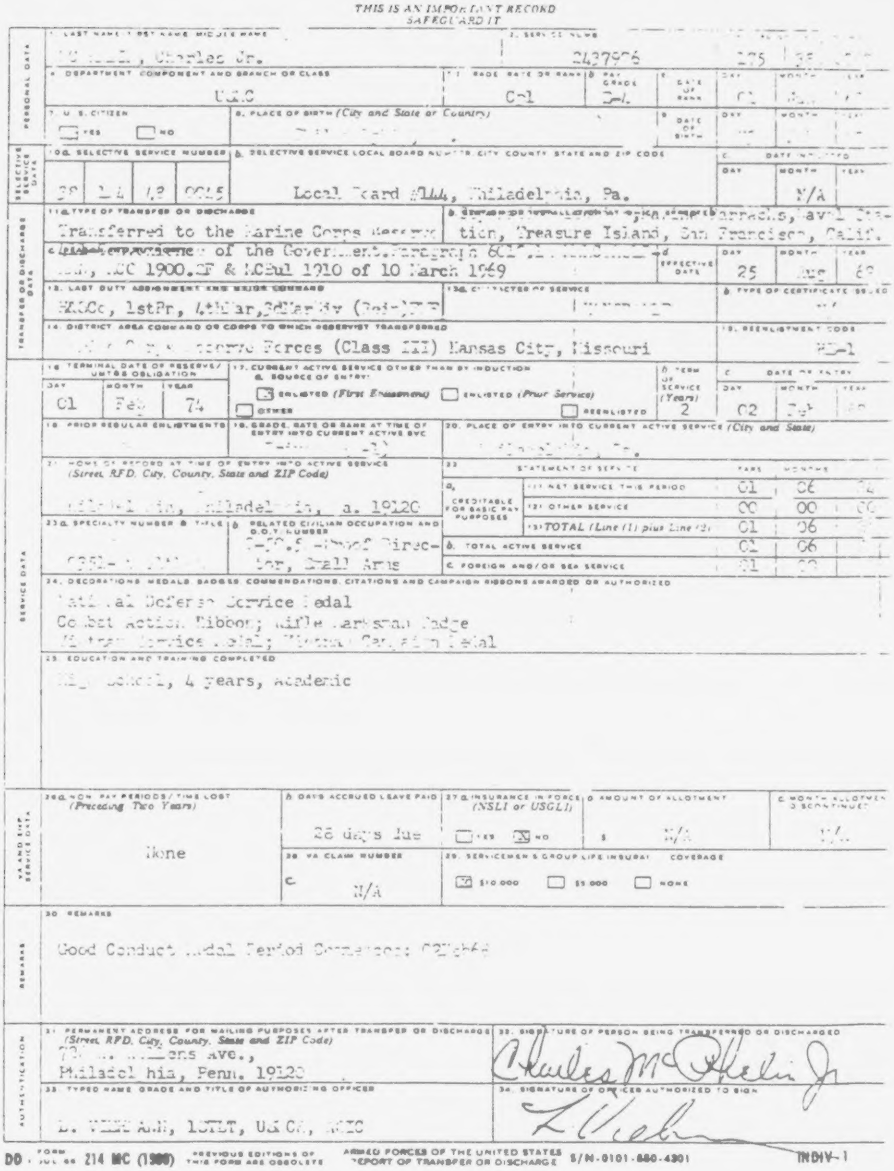
There is no history of cancer in his family. Chalie's mother is 68 years old, alive and well. His father died three years ago at age 64. It was not from cancer. His two older sisters are alive and well.

My son, Matthew had two moles on his buttocks, which I had removed last year. The biopsy was negative. The doctor at the Police & Fire Clinic advised me to wait, to see if they changed color, but I was afraid something might happen.

There are questions that need to be answered. Are our children going to have effects from the Agent Orange? No one seems to know, if they do know, they are reluctant to talk about it. I am very concerned.

Sincerely,
Charline Mc Phelin

Charline Mc Phelin
920 St. Vincent Street
Phila, Pa. 19111



THIS IS AN IMPORTANT RECORD
SAFEGUARD IT

PERSONAL DATA

1. LAST NAME - FIRST NAME - MIDDLE NAME: [illegible], Charles Jr.
2. SERVICE NUMBER: 2437976
3. [illegible]: 275 [illegible]
4. DEPARTMENT, COMPONENT AND BRANCH OR CLASS: USMC
5. a. GRADE, RATE OR RANK: Cpl
5. b. PAY GRADE: E-4
6. DATE OF RANK: DAY 01 MONTH [illegible] YEAR [illegible]
7. U.S. CITIZEN ☐ YES ☐ NO
8. PLACE OF BIRTH (City and State or Country): [illegible]
9. DATE OF BIRTH: DAY [illegible] MONTH [illegible] YEAR [illegible]

SELECTIVE SERVICE DATA

10. a. SELECTIVE SERVICE NUMBER: 38 | 144 | 48 | 0045
b. SELECTIVE SERVICE LOCAL BOARD NUMBER, CITY, COUNTY, STATE AND ZIP CODE: Local Board #144, Philadelphia, Pa.
c. DATE INDUCTED: DAY MONTH N/A YEAR

TRANSFER OR DISCHARGE DATA

11. a. TYPE OF TRANSFER OR DISCHARGE: Transferred to the Marine Corps Reserve
b. STATION OR INSTALLATION AT WHICH EFFECTED: Marine Barracks, Naval Station, Treasure Island, San Francisco, Calif.
c. REASON AND AUTHORITY: Convenience of the Government. Paragraph 601 [illegible], MCO 1900.2F & MCBul 1910 of 10 March 1969
d. EFFECTIVE DATE: DAY 25 MONTH Aug YEAR 69
12. LAST DUTY ASSIGNMENT AND MAJOR COMMAND: H&SCo, 1stBn, 4thMar, 3dMarDiv (Rein) FMF
13. a. CHARACTER OF SERVICE: [illegible]
b. TYPE OF CERTIFICATE ISSUED: [illegible]
14. DISTRICT, AREA COMMAND OR CORPS TO WHICH RESERVIST TRANSFERRED: Marine Corps Reserve Forces (Class III) Kansas City, Missouri
15. REENLISTMENT CODE: RE-1

SERVICE DATA

16. TERMINAL DATE OF RESERVE/UMTS OBLIGATION: DAY 01 MONTH Feb YEAR 74
17. CURRENT ACTIVE SERVICE OTHER THAN BY INDUCTION
a. SOURCE OF ENTRY: ☒ ENLISTED (First Enlistment) ☐ ENLISTED (Prior Service) ☐ OTHER ☐ REENLISTED
b. TERM OF SERVICE (Years): 2
c. DATE OF ENTRY: DAY 02 MONTH Feb YEAR [illegible]
18. PRIOR REGULAR ENLISTMENTS: [illegible]
19. GRADE, RATE OR RANK AT TIME OF ENTRY INTO CURRENT ACTIVE SVC: [illegible]
20. PLACE OF ENTRY INTO CURRENT ACTIVE SERVICE (City and State): Philadelphia, Pa.
21. HOME OF RECORD AT TIME OF ENTRY INTO ACTIVE SERVICE (Street, RFD, City, County, State and ZIP Code): [illegible] Philadelphia, Philadelphia, Pa. 19120
22. STATEMENT OF SERVICE

		YEARS	MONTHS	DAYS
a. CREDITABLE FOR BASIC PAY PURPOSES	(1) NET SERVICE THIS PERIOD	01	06	24
	(2) OTHER SERVICE	00	00	00
	(3) TOTAL (Line (1) plus Line (2))	01	06	[illegible]
b. TOTAL ACTIVE SERVICE		01	06	[illegible]
c. FOREIGN AND/OR SEA SERVICE		01	00	

23. a. SPECIALTY NUMBER & TITLE: 0351 [illegible]
b. RELATED CIVILIAN OCCUPATION AND D.O.T. NUMBER: [illegible] Director, Small Arms
24. DECORATIONS, MEDALS, BADGES, COMMENDATIONS, CITATIONS AND CAMPAIGN RIBBONS AWARDED OR AUTHORIZED:
National Defense Service Medal
Combat Action Ribbon; Rifle Marksman Badge
Vietnam Service Medal; Vietnam Campaign Medal
25. EDUCATION AND TRAINING COMPLETED: High School, 4 years, Academic

VA AND EMP. SERVICE DATA

26. a. NON-PAY PERIODS/TIME LOST (Preceding Two Years): None
b. DAYS ACCRUED LEAVE PAID: 28 days Due
27. a. INSURANCE IN FORCE (NSLI or USGLI): ☐ YES ☒ NO
b. AMOUNT OF ALLOTMENT: $ N/A
c. MONTH ALLOTMENT DISCONTINUED: N/A
28. VA CLAIM NUMBER: C- N/A
29. SERVICEMEN'S GROUP LIFE INSURANCE COVERAGE: ☒ $10,000 ☐ $5,000 ☐ NONE

REMARKS

30. REMARKS: Good Conduct Medal Period Commences: 02Feb68

AUTHENTICATION

31. PERMANENT ADDRESS FOR MAILING PURPOSES AFTER TRANSFER OR DISCHARGE (Street, RFD, City, County, State and ZIP Code):
[illegible] Ave.,
Philadelphia, Penn. 19120
32. SIGNATURE OF PERSON BEING TRANSFERRED OR DISCHARGED: Charles McPhelin Jr
33. TYPED NAME, GRADE AND TITLE OF AUTHORIZING OFFICER: L. [illegible], 1STLT, USMCR, [illegible]
34. SIGNATURE OF OFFICER AUTHORIZED TO SIGN: L. Veb

DD FORM 214 MC (1966) PREVIOUS EDITIONS OF THIS FORM ARE OBSOLETE — ARMED FORCES OF THE UNITED STATES REPORT OF TRANSFER OR DISCHARGE — S/N-0101-880-4301 — INDIV-1

My name is Ann Riley. On August 10, 1971, I married the man of my dreams. I hesitate to say that the dream certainly proved to have nightmarish overtones, however truth is truth.

On April 26, 1972, my first child was born. We named our newborn son Louis Jason Riley. He was a beautiful child weighing 7 lbs. 9 3/4 ozs. As proud parents of our first-born, we settled in for family life. On May 9, 1972, I took my son for a check-up because he was often throwing-up his formula. I will never forget the look on my pediatrician's face as he told the nurse to get my mother. He said Jason was in cardiac arrest. I remember asking him did that mean Jason had to go to the hospital.

Jason did, indeed, go to the hospital from which he never returned. Jason was flown to Eugene Talmadge Hospital in Augusta, Ga. He died on the operating table on May 10, 1972. I remember the doctor asking Dan if he had been exposed to anything in Vietnam. My husband answered ignorantly, "no."

The sad part of this is the fact that my son, Louis Jason Riley, died for his country. My 2 week old baby had been in Vietnam. Certainly, as his mother, I feel he is an unsung hero. He gave his life so our troops could see through vegetation.

On his grave marker, the words are inscribed, "My son, My heart, My Angel." For indeed, part of me died on May 10, 1972.
Thank you, Mr. President.

Our second child, Anissa Joy Riley, was born on May 25, 1973. Anissa is soon to be fifteen. Anissa has a learning disability. We have fought through the years. Her third grade teacher tried to tell us Anissa was retarded. If the school system had their way, Anissa would be in a special school for retarded children. My heart bled for my second-born as she struggled to keep up with her class-mates. I had her tested by a school psychologist. In order to prevent Anissa from being labeled "retarded" for the rest of her life, we enrolled her in a private school where they determined Anissa was a "slow learner" not retarded.
Thank you, Mr. President.

On July 7, 1974, our third child, Danielle Joan Riley was born. A beautiful baby girl who weighed 8 lbs. 4 1/2 ozs. Danielle will be fourteen in July. She is an extremely bright child. However, when my daughter began puberty, one breast grew and one did not. The doctor has told us when she is sixteen, she can have plastic surgery performed. In the meantime, my beautiful, bright daughter makes F's in P. E. because she is embarassed to dress-out with other girls. Children are so cruel at the age. She is afraid her reputation would be ruined forever if anybody should see.

Perhaps, by now, you are wondering about my" "dream man." Well, here we are seventeen years later. My husband has had pneumonia sixteen times. At the age of 32, my husband was diagnosed as having anti-trypsin defiency. We were devasted. The aliment struck just as we were finally beginning to get financially established.

Protein is normally broken dwon by the enzyme trypsin. Trypsin is produced by the liver and is found in the bloodstream. Dan's liver no longer produces trypsin, his body is literally consuming itself. My once robust, virile, 6'1" husband, is now a 95 lbs. semi-invalid. I include semi with invalid only because he refused to be "labeled" an invalid. Walking to the mailbox can only be accomplished by taking frequent stops. You see, the first organs to be affected were his lungs. My husband strggles to breathe even in a sitting position. Living with only a 30% lung capacity, even the slightest effort exhausts him.

Dan was given one to three years to live at the time the doctor initially diagnosed his condition. Last November marked the fourth year. There is not an organ in his body that is not deteriorating. He has heart fibrilations,stomach spasms, loss of bowel control, no muscle tissue, and many other health problems.

I look at my "dream man" sometimes now and see the robust, virile man I married. I do have to dream now because what I see is a sweet spirit in a shell of a man.

We have tried unsucessfully to get help from the Veterans Administration. Dan has become disgusted because he has been turned down three times. You see, he was proud to be an American. He volunteered to fight in Vietnam for his country.

Now America, your boys have come home. They are dying. Not on the battlefields of Vietnam but on home soil. Their bodies are bëing ravished with the effects of dioxin in their bloodstreams. America, you have turned your head long enough. Open your eyes and see the plight of your veterans and families.

Sincerely,

Ann Riley

Ann Riley

TESTIMONY OF DANNY REED
VETERANS OF THE VIETNAM WAR, INC.
NATIONAL ASSOCIATION OF AGENT ORANGE SURVIVORS

BEFORE THE COMMITTEE OF

VETERANS' AFFAIRS

MAY 12, 1988

I come before this committee today as a proud, yet humbled, bent, but not broken, concerned, but also very confused veteran of the Vietnam War.

Although my official status is that of a civilian, I feel as though I am still on active duty. For the past several years, the Veterans of the Vietnam War have been unable to disengage the "enemy". We are unable to take a much needed "R & R", and we are suffering battle fatigue with very heavy casualties.

Yes, I submit to you, the body count continues.......

The Veterans of the Vietnam War, Inc., the National Association of Agent Orange Survivors, and many other dedicated organizations continue to supply us with generous amounts of high quality support and guidance, but we continue to lose ground. For it seems our adversary in this conflict is much stronger than we thought. In fact, we have grossly underestimated the enemy's strength.

It is time for us to call on our allies to send their best troops to stand beside us in battle. Who are our allies?

The American people! Who are their best troops? You are!

Now it is time for you to join us in combat. You must use all of your talents, all of your skills, and all of your immense power to help us win the war and end the body count.

We want history to remember Veterans of the Vietnam War as valiant warriors who never gave up the fight, no matter how the odds were stacked against us.

We want the record to show that the 100th Congress of the United States of America stood side by side with us, our families, and our survivors to defeat one of our nation's worst and strongest enemies- The Dioxin Dilemma.

In closing, we ask you for the peace we have fought so hard to achieve. Peace so that we, the soldiers, can rejoin society by putting our war wounds behind us, with the knowledge that our loved ones, including this great nation, will suffer no more.

Thank you.

Testimony of

David F. Carter, Chairman
Michael N. Sovick, Research Director

THE OKLAHOMA AGENT ORANGE FOUNDATION

Member of the National Association
of State Agent Orange Programs

before the

UNITED STATES SENATE
COMMITTEE ON VETERANS AFFAIRS

Honorable Alan Cranston, Chairman

Thursday, March 31, 1988

MEMBER OF THE NATIONAL ASSOCIATION OF STATE AGENT ORANGE PROGRAMS

THE OKLAHOMA AGENT ORANGE FOUNDATION
P.O. Box 849
Lexington, OK 73051
March 31, 1988

The Honorable Alan Cranston
Chairman: Veterans Affairs Committee
United States Senate
Washington, D.C. 20510

RE: Written testimony for the Permanent Record of the Veterans Affairs Committee Hearings on Oversight and Legislation for Agent Orange Disabilities, March 31, 1988

Dear Senator Cranston,

This letter will introduce the following:

1. Opening remarks: Agent Orange - Medical or Political? (Three pages, 1-3)

2. An overall summary and critique of the Ranch Hand Studies. (One page, 4)

3. A review and critique of the Ranch Hand Baseline Morbidity Study Results. (Five pages, 5-9)

4. A review and critique of the Ranch Hand Followup Morbidity Examination Results. (Four pages, 10-13)

5. A review, critique, and summary of the CDC Vietnam Experience Study, 1987. (Three pages, 14-16)

The above mentioned items are intended to be the written testimony of The Oklahoma Agent Orange Foundation, David F. Carter, Chairman and Michael N. Sovick, Research Director. We respectfully submit these items for the permanent record of the Senate Veterans Affairs Hearings on Oversight and Legislation for Agent Orange Disabilities.

The intented purpose of these statements, reviews, critiques, and summaries is to help to set the record straight with respect to the human health effects of exposure to Agent Orange and the other toxic substances used in Vietnam.

Sincerely,

David F. Carter, Chairman
and Michael N. Sovick,
Research Director
Michael N. Sovick

MEMBER OF THE NATIONAL ASSOCIATION OF STATE AGENT ORANGE PROGRAMS

THE OKLAHOMA AGENT ORANGE FOUNDATION
P.O. Box 849
Lexington, OK 73051
March 31, 1988

AGENT ORANGE - MEDICAL OR POLITICAL?

The Veterans Administration must be mandated to provide specific health care to America's Veterans.

> "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the Pursuit of Happiness."
>
> -- The Declaration of Independence

Many Americans, past and present, grew to maturity with this thought, and love and respect the document that it spawned, the Constitution of these United States of America.

Now we find a great fraud has been committed on the people. Today's bureaucrats, and many of our highly elected officials fail to implement the protections of this near sacred document. A case in point, is a group of citizens who offered their lives in it's support, America's Veterans. They have been denied a basic Right to Life.

President Eisenhower identified the root cause of constitutional destruction some thirty years ago when he coined the phrase "military-industrial complex". Basically he said that if this institution of violence were allowed to exist in peace time it would soon take control of the government of the United States and ostracize - "We, the people".

Our defense contractors have developed many instruments for both war and protection; however, in order to keep a just profit they have had to find civilian uses for their wartime technologies, or convert their manufacturing expertise to products that are marketable during peaceful times. It is easy to see that continued manufacturing of existing technology, along with lobbying into existence a market, is by far the easiest, and most apt to bring financial gain. Civilian sales of war technology can only be profitable if information on the possible damage, by these products, to civilians is suppressed. Hence the first victim group, those that might act as a barometer of damage must be silenced. The method? Removal, by law, of the constitutional protection of the first victim group, the American Veteran.

This, in and of itself, is not only unconstitutional, but in fact was the beginning of the end of our beloved Republic. Those who supported the original removal, and those who continue to obstruct efforts to return, by law, these protections are most certainly traitors, the domestic enemy.

One specific, but sadly not isolated example, is the current problem with war gases (chemical warfare agents) i.e., Agents: Orange, White, Blue, Purple, Pink, Green, Orange II and their damaging effects on our species. Remove the color codes and one finds names such as 2,4-D, 2,4,5-T, picloram, cacodylic acid, arsine gas, dioxin, and more. Also, used in war were Chlordane, DDT, Lindane (666), Dieldrin, and others. Many users were and are educated in schools and at seminars that are supported financially by the manufacturers, and are therefore not only "diseducated", but have no knowledge of alternative methods for completing a given task. This may be the ultimate chemical dependency.

Information control now runs deep. The monies of defense contractors not only support college laboratories but also political campaigns, and are used to influence bureaucrats. These monies also control the media through advertising dollars, and are surely the method of release of "disinformation", so popular with the present Reagan administration; which actually had a cancer warning removed from from the Veterans Administration literature (compare VA pamphlet "Worried About Agent Orange?", July 1980 with VA COMM 1 3-82). Six years later, thousands of American Veterans who could not avail themselves of early warning and/or detection were found to have cancer.

The truth is that these chemicals are carcinogenic and/or cancer promoters. They cause chromosome damage, are teratogenic and mutagenic, damage the thyroid, kidneys, heart, blood-forming organs, liver, and the brain. They may be the main cause of Autoimmune diseases such as rheumatoid arthritis, mixed connective tissue disease, systemic lupus erythematosus, and others. They can cause behavioral changes and anti-social behavior. They are excreted in the semen and as such, are not only sexually transmitted but also expose the fetus in the uterus. They damage and/or compromise the human immune system and they are in fact at least a cofactor, and more probably the direct cause of leukemias, including the current AIDS "epidemic". If these charges are false would not the "evil" ones insist on, instead of denying, a court case that could rebuke them?

It is no great surprise that the U.S. defense contractors try to hide from legal prosecution for crimes against humanity by claiming immunity because of acting as agents of the government (this is the Nuremburg defense).

Is it any wonder that these "agents of the devil" place their "whores" through out the system i.e., regulatory agencies both state and federal, colleges and even elected officials that can table and veto any corrective measures.

The Rights of the First, Fifth, and Fourteenth Amendments to the Constitution must be returned to our citizens, by law, if the Republic is to endure.

American Veterans are only the first group of citizens to be denied the Rights of redress, and equal protection under the law. Worse yet, without due process, they are being denied the basic Right to Life.

A citizens Right of benefit of doubt, of innocent until proven guilty, is now given to a chemical (read corporate profit). In order to do this these Rights must first be removed from the citizen. Corporate "whores" have suppressed life saving information, released fraudulant information, and thus have murdered not only American Veterans and their families, but those civilians exposed to war gases (chemical warfare agents) while pursuing the American dream. The "multi-national society of greed" is trying to hide under the American flag, as U. S. defense contractors. They care not for our country, or it's people. They have truly caused destruction that may equal or exceed even Hitler's crimes.

The American Revolution must live on and we are armed with the ultimate revolutionary weapon, the vote.

Section Three of the Fourteenth Admendment clearly states that no one shall serve in either the House or Senate if he or she rebels against the Constitution, this would include the constitutional Rights of citizens.

> "That to insure these Rights, Governments are instituted among Men, deriving their just powers from the consent of the governed." "That whenever any form of Government becomes destructive of these ends, it is the Right of the people to alter or abolish it, and to institute new Government, laying its foundation on such Principles and organizing its Powers in such form, as to them shall seem most likely to effect their Safety and Happiness."
>
> -- The Declaration of Independence

Respectfully,

David F. Carter

David F. Carter

MEMBER OF THE NATIONAL ASSOCIATION OF STATE AGENT ORANGE PROGRAMS

THE OKLAHOMA AGENT ORANGE FOUNDATION
P.O. Box 849
Lexington, OK 73051
March 31, 1988

SUMMARY AND CRITIQUE OF THE RANCH HAND II STUDIES

The information contained on this page will summarize the results of the Ranch Hand II studies. These results will be compared with the 1979 GAO instructions given to VA health care facilities. Also, within these studies the USAF reports an increasing dose-response relationship in twelve instances for the officer group, fifteen instances for the enlisted flying group, and seven instances for the enlisted groundcrew group. An increasing dose-response relationship is a true "herbicide effect".

The GAO, on April 6, 1979 in "Health Effects of Exposure to Herbicide Orange in South Vietnam Should Be Resolved", CED-79-22, gave instructions to VA health care facilities, to pay particular attention to a number of organ systems when examining Vietnam veterans for health effects due to exposure to Agent Orange.

COMPARISON BETWEEN RANCH HAND RESULTS AND THE GAO INSTRUCTIONS

	CATEGORY	RANCH HAND	GAO INSTRUCTIONS TO VA
A.	GEN. HEALTH	Poorer health	Repeated infections
B.	CANCER	Excess neoplasms	Neoplasia
C.	NEUROLOGY	Excess nerve disease	Nervous system
D.	PSYCHOLOGY	Suggests more illness	
E.	DIGESTIVE	Excess MORTALITY	Liver
F.	DERMATOLOGY	More Post-SEA acne	Chloracne
G.	CARDIOLOGY	Excess heart disease	Adrenals
H.	HEMATOLOGY	"Herbicide effect"	Blood-forming organs
I.	RENAL	Excess kidney disease	Kidneys
J.	ENDOCRINE	"Herbicide effect"	Thyroid
K.	IMMUNOLOGY	Excess disease	Immune system
L.	PULMONARY	Excess TB, pleurisy	Lungs
M.	REPRODUCTIVE	Excess: birth defects, miscarriages, induced abortions, physical handicaps, neonatal deaths, and more abnormal live birth outcomes	Frequent abortions, congenital deformities

Did the failure of the VA, during the Reagan administration, to diagnose and treat Vietnam veterans for latent disorders mean that this administration is possibly responsible for more suffering than that inflicted on these men by the enemy in Vietnam?

MEMBER OF THE NATIONAL ASSOCIATION OF STATE AGENT ORANGE PROGRAMS

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March 31, 1988

SUMMARY AND CRITIQUE OF RANCH HAND II: BASELINE RESULTS

This summary of Ranch Hand II, the Baseline Morbidity Study Results, must be read after understanding the following: (1) part of the control population of the Ranch Hand Study is employed by the manufacturers of the herbicides used in South Vietnam, (2) the level of statistical significance used by the USAF to describe positive associations of morbidity was a p-value equal to or less than 0.05, and (3) the original comparison group is the only valid comparison group.

First, the fact that part of the control group works around, and has been continually exposed to the herbicides and their contaminants, during the manufacturing process, may have resulted in considerable negative bias in the Ranch Hand Study. In other words, this bias probably resulted in an under estimation of the diseases and conditions caused by herbicide exposure in the Ranch Hand group in Vietnam.

Second, in regard to level of statistical significance used in assessing human health; recently, the p-value of 0.10 is being excepted as a better indicator for assessing human health data. Some researchers have even suggested a p-value equal to or less than 0.15 for studies assessing disease prevention. In fact, even the USAF authors of this Ranch Hand Study report that p-values between 0.10 and 0.20 are suggestive of differences between the groups being studied (see page XVI-4-4 of Ranch Hand II). The use of p-value 0.05 as an indicator of human morbidity in Ranch Hand II is another negative bias which under-assesses the diseases and conditions experienced by these Vietnam Veterans.

Third, as the Ranch Hand Study progressed through the years the deceaced members of the control group were replaced from an elegible pool of possible participants who were essentially self-selected because they volunteered; instead, they should have been randomly choosen. This method of replacement also results in a possible negative bias because the replacements would be more healthy than those they replaced.

Because of the above mentioned negative influences this summary will: (1) report diseases and conditions found with p-values equal to or less than 0.20 and (2) report differences with the original control group. Furthermore, all differences between the study group and control group will be expressed as Ranch Hand vs. the Comparison group.

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BRIEF REVIEW ----- USAF RANCH HAND II: BASELINE RESULTS

A. GENERAL HEALTH	In terms of overall health, Ranch Handers perceive their state of health to be POORER that of the Comparisons.
B. MALIGNANCY	The occurrence of verified SKIN CANCER was SIGNIFICANTLY HIGHER in the Ranch Hand group (p=0.04). Observed systemic cancer versus SEER (Surveillance, Epidemiology, and End Results, a National Cancer Institute data base); showed a "STATISTICALLY SIGNIFICANT EXCESS" of lip and oral cancers, Ranch Hand in excess (RH>C). *** HOWEVER, IN THE "EXECUTIVE SUMMARY", USAF AUTHORS WROTE JUST THE OPPOSITE: "There were no statistically significant differences in the occurrence of malignant or benign systemic tumors between the groups." IN FACT, THERE ARE TWICE AS MANY CANCERS OF THE LIP, ORAL CAVITY, AND PHARYNX. THERE ARE THREE TIMES AS MANY RESPIRATORY AND INTRATHORACIC NEOPLASMS. ALSO, THREE TIMES AS MANY GENITOURINARY ORGAN CANCERS, INCLUDING TWO (2) TESTICULAR NEOPLASMS (NONE IN THE COMPARISON GROUP). THE TWO (2) RANCH HAND BLADDER CANCERS WERE NOTED AT EARLIER-THAN-EXPECTED AGES.
C. NEUROLOGY	The USAF claims that the only neurological abnormality is a borderline increase in the proportion of Ranch Handers with a positive Babinski reflex. *** HOWEVER, THERE ARE MANY OTHER SIGNIFICANT AND SUGGESTIVE NEUROLOGICAL ABNORMALITIES LISTED WITHIN THE STUDY.

D.	PSYCHOLOGY	The USAF claims that the only psychological abnormalities in the Ranch Hand group are SIGNIFICANT hypochondria, depression, hysteria, and schizophernia vis-a-vis the comparison group, after adjustment for education. *** HOWEVER, THERE ARE MANY OTHER SIGNIFICANT AND SUGGESTIVE PSYCHOLOGICAL ABNORMALITIES LISTED WITHIN THE STUDY.
E.	DIGESTIVE SYSTEM	Twice as many Ranch Handers as comparisons had ENLARGED LIVERS on physical examination. STATISTICALLY SIGNIFICANT group differences were found in the occurrence of MISCELLANEOUS LIVER DISORDERS. (RH>C)
F.	DERMATOLOGY	Reported ACNE post SEA shows a relative risk of 1.18. (RH>C)
G.	CARDIOVASCULAR	Two (2) PERIPHERAL PULSES are SIGNIFICANTLY DEMINISHED OR ABSENT in the Ranch Handers.
H.	HEMATOLOGY	Two (2) STATISTICALLY SIGNIFICANT OVERALL EXPOSURE GROUP EFFECTS are seen and seven (7) exposure-smoking interaction effects are found. "The 2 overall exposure group effects occur in the Ranch Hand officer cohort and involve the variables MCH and MCHC." "An increasing dose-response relationship is clear...". AN INCREASING DOSE-RESPONSE RELATIONSHIP IS A "HERBICIDE EFFECT". "These findings are suggestive of a herbicide effect,...". "This interaction is compatible with a herbicide effect, and reinforces the finding in the enlisted flying personnel." *** HOWEVER, THERE IS NO MENTION OF THIS "HERBICIDE EFFECT" IN EITHER THE "EXECUTIVE SUMMARY" OR IN THE "INTERPRETA"TIONS OF STUDY RESULTS & CONCLUSION".

I.	RENAL	The Ranch Hand group reported significantly MORE past KIDNEY DISEASE than the comparison group.
J.	ENDOCRINOLOGY	Ranch Handers were found to DIFFER from the comparison group with respect to proportions of individuals in normal & abnormal thyroid hormone categories. "...(D)ecreasing T3 uptakes are associated with advancing age in both groups with the slope being much steeper in the Ranch Hand group." "...(I)t also cannot be confidently asserted that a herbicide effect on thyroid function has not occurred." Ranch Hand personnel have HIGHER TESTOSTERONE LEVELS than comparisons. "This finding... ...may reflect a herbicide effect,...". POSITIVE ASSOCIATIONS of GLUCOSE LEVELS with age are GREATER in the Ranch Hand group than in the comparison group. "Thus, a subtle toxicological effect of herbicide on glucose metabolism may have been detected." *** HOWEVER, THERE IS NO MENTION OF THIS "HERBICIDE EFFECT" IN EITHER THE "EXECUTIVE SUMMARY" OR IN THE "INTERPRETA-"TIONS OF STUDY RESULTS & CONCLUSION".
K.	IMMUNOLOGY	"A statistically significant group difference is noted in Control #1." (unstimulated proliferation rate) *** HOWEVER, THERE IS NO MENTION OF THIS FUNCTIONAL IMMUNE SYSTEM DEFICIT IN THE "EXECUTIVE SUMMARY" OR IN THE "INTERPRETATIONS OF STUDY RESULTS & CONCLUSION". *** ALSO, THERE ARE MANY OTHER SIGNIFICANT AND SUGGESTIVE IMMUNOLOGICAL ABNORMALITIES LISTED WITHIN THE STUDY.
L.	PULMONARY	"In a few instances the results of the statistical analyses revealed significant (p =/< 0.05) or suggestive (p=0.10-.20) differences in pulmonary function."

M. FERTILITY AND REPRODUCTIVE OUTCOMES

Results of the Conception/Exposure Index Analyses -- "The only statistically significant findings are for miscarriage and for induced abortion among officers. ...there was a significant association between miscarriage and exposure level (low, medium, and high)."

THIS IS AN INCREASING DOSE-RESPONSE RELATIONSHIP -- A "HERBICIDE EFFECT".

Results of the Live Birth/Exposure Index Analyses -- "Birth defects are found to have a statistically significant association with herbicide exposure level in the officer and enlisted flying groups."

"Executive Summary" -- "Reported neonatal deaths and physical handicaps were also significantly excessive in the Ranch Hand group when contrasted to the total comparison group."

"Summary of Fertility and Reproductive Analyses" -- "Significant differences were reflected in the analyses of live birth outcomes."

"Spouse and Participant Reported Birth Defects Not Meeting Study Criteria" -- Mental including "Learning Disability".

"Summary" -- "These findings in this chapter do require further evaluation of the possible link between herbicide/ dioxin exposure and birth defects."

*** HOWEVER, IN THE "EXECUTIVE SUMMARY", USAF AUTHORS WROTE JUST THE OPPOSITE: "There were no significant findings in conception outcomes for miscarriages, stillbirths, induced abortions, or live births. For live birth outcomes no differences were observed for prematurity, learning disability, or infant deaths."

DESPITE ALL OF THE PRECEEDING EVIDENCE OF EXCESS DEATH AND DISEASE the USAF insists that, "...the baseline study results should be viewed as reassuring to the Ranch Handers and their families at this time". HOWEVER, WITHIN THEIR STUDY THE USAF REPORTS AN INCREASING DOSE-RESPONSE RELATIONSHIP IN TWELVE (12) INSTANCES FOR THE OFFICERS, FIVE (5) INSTANCES FOR THE ENLISTED FLYING, AND TWO (2) INSTANCES FOR THE ENLISTED GROUNDCREW. AN INCREASING DOSE-RESPONSE RELATIONSHIP IS A "HERBICIDE EFFECT".

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SUMMARY AND CRITIQUE OF RANCH HAND II: FOLLOWUP RESULTS

This summary of the USAF Ranch Hand Study II, First Followup Examination Results, must be read after completely understanding the following: (1) part of the control population (Comparisons) used in the Ranch Hand Study are currently employed by the manufacturers of the herbicides which were used in South Vietnam, (2) the level of statistical significance used by the USAF to describe positive associations of morbidity was a p-value equal to or less than 0.05, and (3) the original Comparison group is the only valid comparison group.

As the Ranch Hand study has progressed thru the years some members of the comparison group have been replaced, due to death or nonparticipation, from an elegible pool of possible participants. These replacements were essentially self-selected because they volunteered; instead they should have been randomly choosen. This method of replacement may have biased the results by making the total Comparison group statistically "more healthy" than the original comparison group. Also, some of the Ranch Hands "chose" not to participate in the Followup study including some of the individuals who had verified neoplasms during the the Baseline study. The exclusion of these individuals would make the Ranch Hand group appear statistically "more healthy".

However, even with the positive effect of the "more healthy" Ranch Hand and Comparison groups the Followup Results showed a WORSENING of the health of the Ranch Hands versus Comparisons with respect to exposure analyses, in almost all of the study categories. Also, worth noting is the fact that Fertility and Reproductive Outcomes were not done during the Followup Examination. Also, again in the Followup study, as in the Baseline study many of the immunological tests were claimed by the USAF to be unusable because of poor procedure or protocol.

Finally, within the Followup Results there was no listing of the raw data and very few calculated results. Most charts were labeled with NS (nonsignificant) and/or S (significant), instead of the actual numbers; also many analyses were not performed, i.e., the adjusted systemic cancer results.

It is our opinion that the raw data from the Ranch Hand Studies should be made available for independent review. For that matter the raw data from all U.S. government funded studies should be made available to the public; because these studies are paid for by the tax dollars of the public.

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BRIEF REVIEW ----- USAF RANCH HAND II: INTERVAL BETWEEN THE BASELINE AND FIRST FOLLOWUP RESULTS

A.	GENERAL HEALTH	There has been no change in the Ranch Handers POORER perception of general health.
B.	MALIGNANCY	There has been a change for the WORSE with respect to exposure analyses and systemic cancer in Ranch Handers. (See the summary of cancers -- page 13) IN FACT, ORAL CAVITY, PHARYNX AND TESTICULAR NEOPLASMS ARE EXCESS IN RANCH HANDERS -- p<0.06. THREE TIMES THE NUMBER IN THE COMPARISONS. THERE ARE TWICE AS MANY NEOPLASMS OF THE BRONCHUS AND LUNG. (RH>C) AN EQUAL NUMBER OF SOFT TISSUE SARCOMAS. A VERIFIED LYMPHOMA -- RANCH HAND ONLY!
C.	NEUROLOGY	There has been a change for the WORSE with respect to exposure analyses and Ranch Handers neurological functions. IN FACT, INTERVAL NEUROLOGICAL DISEASE FOR NON-INFLAMMATORY DISORDERS SHOWE BORDERLINE SIGNIFICANCE (p=0.069) WITH RANCH HANDS FARING WORSE THAN COMPARISONS.
D.	PSYCHOLOGICAL	There has been a change for the WORSE with respect to exposure analyses and Ranch Handers psychological functions.
E.	DIGESTIVE SYSTEM	There has been a change for the WORSE with respect to Ranch Handers and digestive system disease. IN FACT, THE USAF REPORTS THAT "A REVIEW OF DIGESTIVE SYSTEM MORTALITY SHOWED A RELATIVE EXCESS IN THE RANCH HANDS...".

F.	DERMATOLOGY	There has been a change for the WORSE with respect to exposure analyses and the Ranch Hands dermatology evaluation.
G.	CARDIOVASCULAR	There has been a change for the WORSE with respect to exposure analyses and Ranch Handers cardiovascular function. THERE IS A STATISTICALLY SIGNIFICANT EXCESS OF HEART DISEASE IN RANCH HANDS.
H.	HEMATOLOGY	There has been a change for the WORSE with respect to exposure analyses and Ranch Handers hematological function.
I.	RENAL	There has been a change for the WORSE with respect to the Ranch Handers renal function.
J.	ENDOCRINOLOGY	There has been a change for the WORSE with respect to exposure analyses and Ranch Handers endocrinological function. IN FACT, THE USAF REPORTS THAT "TSH & TESTOSTERONE MEANS TESTS WERE STATISTICALLY SIGNIFICANT, AND IN THE EXPECTED DIRECTION OF A HERBICIDE EFFECT,...".
K.	IMMUNOLOGY	There has been a change for the WORSE with respect to exposure analyses and Ranch Handers immunological responses.
L.	PULMONARY	There has been a change for the WORSE with respect to the Ranch Handers and pulmonary disease. IN FACT, THERE IS A STATISTICALLY SIGNIFICANT EXCESS OF TUBERCULOSIS, PLEURISY, AND RALES IN RANCH HANDERS.

DESPITE ALL OF THE PRECEEDING EVIDENCE OF EXCESS DEATH AND DISEASE the USAF insists that, "(t)he results of the first followup study in 1985 have shown a subtle but consistent narrowing of medical differences between the Ranch Hands and Comparisons since the Baseline study in 1982".

Also, the USAF insists that, "(t)he 1985 examination results provide reassuring evidence that the current state of health of the Ranch Hand participants is unrelated to herbicide exposure in Vietnam". HOWEVER, IN TEN (10) INSTANCES THE USAF REPORTS AN INCREASING DOSE-RESPONSE RELATIONSHIP FOR THE ENLISTED FLYING GROUP. AND, THIS SAME INCREASING DOSE-RESPONSE RELATIONSHIP IS MENTIONED FIVE (5) TIMES FOR THE ENLISTED GROUNDCREW GROUP. AN INCREASING DOSE-RESPONSE RELATIONSHIP IS A "HERBICIDE EFFECT"!

LIST OF CANCERS FOUND IN EXCESS BY STATE AGENT ORANGE PROGRAMS, THE USAF RANCH HAND STUDY - BASELINE AND FOLLOWUP, THE CDC, AND THE VA. (Prepared by The Oklahoma Agent Orange Foundation-1988)

1983 VA A.O. Registry	LYMPHOMAS (NHL) PHARYNX or BUCCAL cavity
1983 Massachusetts	Soft-tissue sarcoma Kidney
1984 Ranch Hand II Baseline	Skin (RH>C - more cancers) Systemic cancers (RH vs. Controls) Twice as many cancers of: Lip Oral cavity (BUCCAL) PHARYNX Three times the cancers of: RESPIRATORY system Intrathoracic (chest) Genitourinary: including; Kidney, and Twice as many Testicular
1985 Wisconsin	Soft-tissue sarcoma
1986 West Virginia	LYMPHOMAS (NHL) REPSIRATORY system LARYNX Testicular
1987 CDC VES	LYMPHOSARCOMAS Leukemia Brain
1987 VA	LYMPHOMAS (NHL) LUNG
1987 Ranch Hand II Followup	Skin (RH>C - more neoplasms) Systemic Neoplasms (RH>C) Three times the cancers of: Oral Cavity (BUCCAL) PHARYNX Twice as many cancers of the: BRONCHUS LUNG Three times the number of: Testicular neoplasms Soft Tissue Sarcomas: An equal number of: LYMPHOMA: Ranch Hand only

MANY OF THESE PUBLISHED RESULTS HAVE SHOWN A SIGNIFICANT EXCESS OF LYMPHOMAS AND/OR RESPIRATORY NEOPLASMS --NO STATISTICAL FLUKE!

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CRITIQUE OF THE CDC VIETNAM EXPERIENCE STUDY

On February 13, 1987, the Journal of the American Medical Association (JAMA) published the first part of the Centers for Disease Control (CDC) Vietnam Experience Study (VES); which, states: "(t)he VES is a historical cohort study designed to identify the possible adverse health effects of having served in the military in Vietnam." This study is the first result of the Congressionally mandated epidemiological studies first proposed by PL-96-151 which was signed into law by President Carter. The CDC also published a monograph about this part of the VES which is titled "Postservice Mortality Among Vietnam Veterans" which was printed in February, 1987. This critique will describe the many differences between these two formats of the same study, which were written by the same authors.

The primary difference between these two versions of the VES was the method used characterize data. In the JAMA article the data was based on the less accurate information found on the death certificates; however, in the CDC Monograph the data was based on a more truthful assessment of the cause of death. The data used in the CDC Monograph reflected the views of a medical review panel which determined the true cause of death from a review of the medical records. The differences in the data between these methods essentially provided the researchers with two data bases. Because the JAMA article was subsequently reported on by the media, the least accurate information was made public. Was this meant to bias public perception of the health problems experienced by Vietnam Veterans?

Another factor was misrepresented in the JAMA article by the following statement, "(t)he excess in postservice mortality due to external causes among Vietnam veterans is similar to that found among men returning from combat areas after World War II and the Korean War". The authors did not explain that these veterans were POWs during their period of service. The fact that Vietnam Veterans have experienced similar excesses in postservice mortality means that Vietnam Veterans are dying at the same rate as POWs from those past two wars (not at the same rate as all "men returning from combat areas"). Was this omission another attempt to bias public perception?

In the CDC monograph the more accurate data base provided a different assessment of the excess deaths due to external causes. In the JAMA article this category was statistically significant; however, the statistical significance was lost when the more accurate data from the medical review panel was used. Also, in the monograph besides the elevated risk ratio for external causes found in the JAMA article; there was a positive risk ratio for mental disorders and cancer.

With respect to the risk ratio of 0.82 for cancer deaths, the JAMA article states "(t)here was no particular type of neoplasm in excess in the Vietnam cohort". However, the CDC monograph shows a risk ratio of 1.21 and states that "(e)xamination of specific types of cancer (Table 30) shows more deaths among Vietnam veterans from brain cancers, leukemia, and non-Hodgkin's lymphomas, all in very small numbers". The calculated risk ratios 4.0, 1.66, and 2.73 respectively for these cancers reveal a very different assessment of health effects of Vietnam Veterans than that found in the JAMA article.

The risk ratio of 0.95 for mental disorders found in the JAMA article was different from the 2.85 risk ratio which was found after the medical review of deaths in the CDC monograph. In fact, a p-value of 0.06 was calculated from the CDC data for mental disorders. There was only agreement between JAMA (death certificate) and CDC (medical review panel) on 4 of 16 of the deaths due to mental disorders. Again, the JAMA article misrepresents the true facts.

The most important omission from the JAMA article concerns the fact that there was no mention of the autoimmune disease described in the CDC monograph. The category of diseases of the musculoskeletal system (ICD 710-739) did not exist in the JAMA article which was based only on the death certificate data. The CDC monograph found some evidence of autoimmune disease in Vietnam Veterans; and, because the ICD categories do not have a specific code number for autoimmune disease there may be other cases of this type of disease which are not otherwise obvious. Within the book "Environmental Epidemiology" a study by Todd M. Frazier, "The Use of National and State Data Systems for Occupational Health Surveillance", found excesses for diseases of the muscloskeletal system and connective tissue (ICD 710-738) among workers in agriculture (who probably were exposed to the phenoxy herbicides), by using Social Security Administration (SSA) Disability Award Files. Also the VA authors (in the soon to published), "Proportionate Mortality Study of Army and Marine Veterans of the Vietnam War", found a statistically significant increase in deaths due to musculoskeletal and connective tissue diseases among Army Vietnam Veterans.

In summary, the JAMA article seems to misrepresent the true facts with respect to the health effects experienced by Vietnam Veterans; because, the data used was based on inaccurate information found on the death certificates. However, the CDC monograph about the VES was based on data from a medical review of the medical records; which found excess risk ratios not only for external causes but also for cancer and mental disorders. Why were two versions of the same study printed using CDC data?

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DIFFERENCES BETWEEN THE "J.A.M.A." (Journal of the American Medical Association) AND THE CDC (Centers for Disease Control) MONOGRAPH VERSIONS OF THE CDC VIETNAM EXPERIENCE STUDY (VES).

	CDC JAMA VERSION		CDC MONOGRAPH VERSION
1.	Medical data used based on death certificates. [Less accurate]	1.	Medical data used based on review of medical records.[More accurate]
2.	"There was no particular type of neoplasm in excess in the Vietnam cohort."	2.	"Examination of specific types of cancer shows more deaths amoung Vietnam Veterans from brain cancers, leukemia, and non-Hodgkin's lymphomas, all in very small numbers."
3.	Risk ratio for neoplasms 0.82.	3.	Risk ratio for neoplasms 1.21. [Excess]
4.	Found excess post-service mortality similar to other men returning from combat areas after WWII and Korea.	4.	Did not explain that Vietnam veterans actually are experiencing similar post-service mortality as ex-POWs from WWII and Korea.
5.	Describe statistically significant excess deaths due to external causes.	5.	Statistical significance for external causes lost.
6.	Report a 0.95 risk ratio for mental disease.	6.	Report a 2.85 risk ratio for mental disease (p<.06). [Excess]
7.	No mention of autoimmune diseases.	7.	Autoimmune diseases, including lupus, were found.
8.	Released to the media for public consumption and published in JAMA.	8.	NO MEDIA RELEASE OF THE MORE ACCURATE DATA IN THE CDC MONGRAPH.

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Mike Shuppert

3 May 1988

Senate Committee on Veterans' Affairs
Room 414, Russell Senate Office Building
Washington, DC 20510

Subject: Testimony for Oversight and Legislative Hearing on "Agent Orange", 12 May 1988

Ladies and Gentlemen:

For almost a decade during the Vietnam conflict, 1,265 Americans served in a unique United States Air Force organization performing a very unusual mission. In 1961 military planners and statesmen determined that the aerial application of agricultural herbicides could advance the U.S. objectives in Indochina.

The organization given that mission was known as Operation Ranch Hand. For nine years (1962-1971) 11.5 million gallons of agricultural herbicides were sprayed by Operation Ranch Hand. By all accounts the mission was a military success. Analysts have stated that the herbicide program saved 50,000 allied casualities. By his own admission, the additional burden placed on the enemy's logistical system as a result of crop destruction slowed his advances. The increase in vertical visibility resulting from the spraying of herbicides exposed the enemy's supply lines and hampered his military objectives.

The Ranch Hand mission was conducted in less than ideal conditions. The C123, a twin engine cargo aircraft modified for aerial spraying, was flown at 150 feet above the enemy's jungle or cropland at a speed of 150 mph. As a result of that altitude necessary to insure proper spray coverage, Ranch Hand aircraft received over 7,000 rounds of enemy ground fire. Twenty-six Airmen lost their lives. One aircraft nicknamed "Patches" was hit over 800 times by enemy fire during her service in Vietnam. That aircraft is now displayed at the Air Force Museum at Wright-Patterson Air Force Base, Ohio.

The outstanding performance and bravery of Operation Ranch Hand personnel was appropriately recognized by our nation. The organization was awarded five Air Force Outstanding Unit Awards, twice with the "V" device for Valor. "The Ranch" received two Presidential Unit Citations and the Government of South Vietnam awarded Operation Ranch Hand the Cross of Gallantry on two separate occasions.

All those familiar with "The Ranch" in Southeast Asia respected her accomplishments, her dedication to mission and the comradery and the esprit de corps borne from this special and difficult mission.

Since 1975 the American public has been bombarded with inflated press accounts highlighting emotional claims made by a few, creating the perception that Operation Ranch Hand "doused" the Vietnam countryside with dioxin -- "dousing" or "drenching" people on the ground, combatants and noncombatants alike. This is simply a myth!

The Ranch Hand aircraft sprayed 95% of all herbicides dispensed in Vietnam. The airborne equipment was maintained to spray at the rate of 3 gallons per acre. Assuming no foilage was above a person's body, .009 of an ounce would settle on your head and shoulder area. That is hardly enough to soak one's clothing! The stories alleging "drenching", "soaking" or "bathing" are simply not valid!

The herbicide 24D/245T (herbicide orange) contained, as a result of production, a trace contaminate of dioxin averaging 2 parts per million (the equivalent of 2 inches in 200 miles). Dioxin was not a "component", a "major element" nor an "ingredient" of 24D/245T, as it has been characterized by the press. It was a trace contaminate and a contaminate degradable by sunlight.

The men of Operation Ranch Hand had one mission in Vietnam -- the herbicide mission. Our contact with those chemicals was daily. The Aircrew were in contact with those chemicals from preflight of the aircraft prior to a mission until the postflight following the mission. Maintenance personnel were in daily contact as they serviced and repaired battle damaged aircraft and spray equipment. Our contact with herbicides was not casual -- it was a normal everyday part of our job in Southeast Asia.

The bottom line in this whole "Agent Orange" controversy is the human health/24D/245T question. Does 24D/245T cause harm to humans? It is a scientific question requiring a scientific approach for resolution.

The vast quantity of scientific literature dealing with 24D/245T (herbicide orange) supports the safety of that herbicide when examined as a whole.

For the past 8 years the Air Force Health Study (AFHS), a hallmark scientific effort by this nation, has been examining the mortality and morbidity of the American service personnel who experienced the greatest degree and frequency of physical contact with herbicides during the Vietnam conflict. Thus far the conclusions of this ongoing study show no significant differences between Ranch Hand personnel and the matched comparison group.

Did the mission of Operation Ranch Hand do harm to the health of those performing that mission? Did the mission of Operation Ranch Hand do harm to those combatants or noncombatants who may have been on the ground? When the facts and science are weighed carefully, unemotionally, and intoto -- the answer remains no.

Respectfully,

Jack Spey

Jack Spey, Major USAF(RET)
President
Ranch Hand Vietnam Association

JS:mt

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[Major Spey's autobiography, submitted with his statement, is being retained in the committee files.]

NATIONAL ASSOCIATION OF STATE AGENT ORANGE PROGRAMS
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Statement of The National Association of State Agent Orange Programs

Present by:

Wayne P. Wilson
Executive Director
New Jersey Agent Orange Commission

and

Victoria Boyne-McGuire
Project Coordinator
New Jersey "Pointman"Project

before the

Senate Veterans Affairs Committee

on

Agent Orange - S-1787

Mr. Chairman, distinguished members of the Committee, thank you for the opportunity to testify today on Senate Bill 1787, The "Veterans Agent Orange Disabilities Act of 1987".

I am here today on behalf of my colleagues of the National Association of State Agent Orange Programs. Briefly stated, our Association was formed in February 1987 in Boston, Massachusetts. The Association is composed of State Government Officials from around the Nation who are actively involved with the Agent Orange issue.

In many respects we are on the "front lines" of this issue given our daily inter-action with the Vietnam Veteran Community. It is precisely because of that involvement that we address S-1787.

Before I get into the specific language of S-1787. I wanted to touch on an area that in some respects goes to the very heart of this issue. There has been over the past number of years considerable discussion and in some cases debates among us over whether we should in fact assist, advise or encourage Vietnam Veterans to file service-connected claims for Agent Orange based on exposure and subsequent illness veterans believe is directly related to their service in Southeast Asia.

Some among us feel that to claim service-connection based on Agent Orange is to absolutely ensure denial of that claim. Even today veterans are "counseled" not to mention Agent Orange to examining VA physicians...even if he/she as asks. Others may counsel Vietnam Veterans to claim exposure as the cause of the illness(s) but usually with the caveat that the whole burden of proof rests squarely on your sholders even to the point of proving your own exposure, finding civilian physicians to help support your claim, obtaining government documents and the list goes on.

The fact is that neither of these approaches are right but never-the-less that is the reality that veterans must deal with. Today you will hear from a widow who will describe her "ordeal" in trying to obtain service-connection based on the exposure of her husband to herbicides during service in Vietnam. If ever there was a case that cried for presumed service-connection, that is one. I have been involved with that claim for most of the past year and personally "pleaded" with a VA Appeals Panel "to do the right thing", to grant service-connection. They did not!

I would like to share with you the thoughts of Dr. Peter A. Kahn a member of the New Jersey Agent Orange Commission and the principal investigator of our "Pointman" research study.

Dr. Kahn has always expressed a deep concern about the political and social "pressures" that science is literally forced to work under relative to this issue. Clearly, we will not have the medical or scientific answers needed to resolve this issue tomorrow, next month or even next year. As you know studies take time, sometimes years and clearly Vietnam Veterans and their families want answers. Knowing this Dr. Kahn has raised the following issue.

"If we deny help to Vietnam Veterans and their families now, by refusing to service-connect their illnesses, what can we all think five years from now if, and when, we find were wrong...that there is a connection between exposure and certain health effects"! If in the end we in science and medicine can not establish a connection then the full error of the Congress would be to err on the side of the Veteran. That is the right way to go. To err the other way is unthinkable, unfair and Vietnam Veterans and their families deserve better".

Among the various States at this moment, studies are either planned or underway...we shall continue on that track because it is proper and necessary. Let me say that S-1787 is the right way to go, it is the right thing to do and we support Senator Daschle's bill.

We commend him and the other sponsors of the bill for their foresight and "sensitivity". Are any of us absolutely 100% sure of the answers that some will try to connect with cause and effect? To go back and forth, and continue debate, fails to respond to an immediate human need. S-1787 meets that need and we in the National Association of State Agent Orange Programs urge the full support of the members of the Committee and the full Senate of the United States of America.

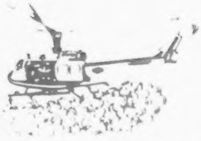
Up to this point, I have attempted to address a side of this issue we see each day, the people, the families, those Vietnam Veterans who are in need. Let mee now deal with the more formal language of the bill.

In Section 3 of the bill, we support the presumption relating to certain diseases, and quite candidly think you might travel a little farther along this line by adding language that includes for example other cancers and illnesses that a physician knows to be unusual for a man or women at a specific age in life. This proposal may warrant more discussion or study and we are pleased that there is a provision in the bill for such discussion and study. We hope you will retain that portion of the bill.

In Section 5 of the bill Results of Examinations and Treatment of Veterans for Disabilities Related to Exposure to Certain Herbicides.

I must tell you that this is an area we have had to deal with out in the States. Many veterans have been critical of the VA's Agent Orange examination and in my office we receive calls and letters daily from veterans across the Country, critical of the treatment afforded them at the hands of the Veterans Administration. In a recent survey done by my office (albeit an unscientific survey) fully 89% of those responding stated that the person examining them "didn't seem to care". Over 80% described the VA exam as not being through. To the question "were the illnesses or disabilities evaluated", 86% said either no or only partially evaluated.

In closing, let me say that this bill goes directly to the concerns we see each day, but more importantly it serves Vietnam Veterans and their families. We hope you will respond favorably and promptly, It is time. Thank you.



VIETNAM VETERANS
AGENT ORANGE VICTIMS, INC.
205 Main Street
Stamford, Connecticut 06901

President
Frank McCarthy
Executive Director
James Sparrow
Secretary
Jane Dziedzic

Senator Alan Cranston, Chairman
Senate Committee on Veterans Affairs
Washington, D.C.

May 12, 1988

Good morning Senator Cranston, distinguished members of the Committee, ladies and gentlemen. The nature of my testimoney today will focus on three specific areas: the Agent Orange Class Action Law Suit (MDL-381), the proposed Senate Legislation [S. 1787] and the Vietnam Veterans claiming damage from exposure to Agent Orange/Dioxin.

The last time I testified before you was on Jan. 26, 1980. I have included a copy of the transcript of that testimony with the hope that you will read it as I did recently. It gives a graphic reflection of what we as Vietnam Veterans and as a nation knew about Agent Orange/Dioxin, the questions you asked me, the composition of our organization, the "Agent Orange cause" and our position on the issue illustrates a startling epitaph of the plight of Agent Orange Veterans and their families.

During that testimony I summarized our objectives in filing suit against the chemical companies. The first and primary objective was to create a Public Trust Fund which would directly address the multitudes of catastrophic problems experienced by the Veterans and their families who claim damage from Agent Orange/Dioxin. Another objective of the litigation was to force the chemical companies to cease manufacturing, selling and promoting the use of herbicides and related products like Agent Orange which contain Dioxin.

To quote Judge George C. Pratt who first presided over the Agent Orange Cases shortly before he turned over control of the case to Chief Judge Jack B. Weinstein, "we've learned a lot since the case was first filed " on June 14, 1978. Indeed, we have learned that Dioxin and Agent Orange are synonymous and sinister. The possibilies are as great, or perhaps even greater, today as they were in Jan. of 1980 that thousands of Vietnam Veterans and their families are suffering ill health problems from exposure.

Our nation's Environmental Protection Agency (EPA), in 1985 issued its final and total ban on the domestic uses of 2,4,5-T and other Dioxin related products. Dow Chemical Company no longer manufacturers, promotes or sells Agent Orange in America. Our nation owes a debt of gratitude to the Vietnam Veterans. They have sacrificed much in leading the fight against Agent Orange/Dioxin related products and human exposures. Future generations will reap the benefits of todays wisdom.

However, that victory has not helped the Agent Orange Veterans with the catastrophic problems which they experience. Their hopes have been shattered by the 2nd Circuit Court of Appeals decision to destroy the Class Assistance Foundation (CAF) created by Judge Weinstein.

"To Alleviate the Suffering, Death and Birth Defects Through Dignity, Self-Respect and Solidarity"

There will never ever be that eternal, legitimate mechanism of healing necessary for Agent Orange Veterans because three individual judges are ignorant and do not care about the damage they are causing. They care more about not setting precedence (having their papers in order) than they do for Vietnam Veterans and their children.

To those of us who have fought for more than a decade to establish this mechanism of healing from this law suit, are still in a state of shock. The $180 million out of court settlement has grown to nearly $250 million. According to the Appeals Court decision approximately $200 million will be distributed to only 12,500 of the 249,000 plaintiffs as disability and death benefits, at a rate of $741 per year for ten years.

The fate of the remaining $50 million is yet to be determined by Judge Weinstein, whom I must say has lead a seemingly lone battle within the judiciary for the Veterans and their families. The Judge has created a Veterans Advisory Board consisting of 12 members, 11 of which are Vietnam Veterans. They will be spending their weekends trying to determine which of the many proposals submitted to the court is worthy of funding.

Ever since the May 7, 1984 settlement Judge Weinstein has continuously requested that the U.S. Government become a part of the settlement. He hasn't asked them to contribute in any specific way, just that they contribute and be a part. The Justice Department has continuously refused. Obviously, the present administration is unwilling to help, in any way, Vietnam Veterans effected by Agent Orange. I would, here by, request that the 100th Congress direct some type of legislation mandating the Veterans Administration to provide assistance to Judge Weinstein and the Veterans Board, even if the assistance is only in the form of administration, logistics or input.

However, it is so disheartening that this huge government, with so many valuable resources and great minds, should not contribute any assistance whatsoever to Judge Weinstein, the Board of Veterans Advisors and 250,000 damaged Vietnam Veterans and their children. Together, we all could accomplish such wonderfully positive changes for so many suffering Americans. Why, Senator Cranston, why must the Justice Department represent the entire U.S. government and deny us help by falling upon the pathetic defense of legal technicalities? Why can't other governmental agencies give input and assistance? Why does every decision pertaining to Vietnam Veterans have to be decided in terms of cost and more importantly why is cost of greater importance than ending the suffering of these families?

The Veterans Administration can be mandated by this 100th Congress to contribute in so many ways other than by monitary compensation. How many Nobel Prizes have been awarded to individuals whose work was conducted within the VA? How many great minds exist within our national military medicine?

(continued)

Why must the Agent Orange Veterans and their children continue to be trapped within the prison of the causality controversy?

I would now wish to speak of the legislation (S. 1787) currently being proposed. Before commenting about this legislation I would be remiss in my duties as a representative of these Veterans and family members if I did not cite the ineffectiveness of every other piece of Agent Orange legislation ever signed into Federal law in this nation. I do not wish to seem ungrateful for the past efforts of this or the previous administration or the 96th, 97th, 98th, 99th or this 100th Congress for I am grateful for any effort. However, the sick, dying and deformed whom I represent judge whether legislation is effective by the number of Veterans or their children who receive help.

I have been told by every level of politician from the President on down of their concern and sympathy for the Agent Orange Veteran and as soon as some study or some compromise happens or some deal is made the Vets will receive the crucial help they need. For more than a decade I have heard this and I am still waiting for that help.

The last legislation would compensate for the illness of porferia and the rash chloracne, so we lined up our chloracne patients at the VA doors and the VA adjudication officers throughout the nation simply said, " denied " to the Vets rashes. They said "no" through eyes blinded by preconceived political & budgetary interests, "we don't see any chloracne" or "that rash isn't chloracne, we don't know what it is but it isn't chlorance". Those rashes did happen to be noncompensable rashes. So we sent those Veterans to other dermatologists and MD's and again lined up at the VA doors and the VA, to this day, has kept the doors closed to us. I remember one Veteran named James Lutz who has letters from seven different doctors who swore his rash is chloracne, the VA simply said, "denied, next case". Mr. & Mrs. Lutz also have four children born with birth defects and disorders.

My point, Senator, is that if this legislation does not put a gun to the head of the VA doctors & compensation adjudication officers, than don't even bother to bring it before the Congress. If this legislation has no teeth than it is, in fact, detrimental to the well being of Vietnam Veterans and their families. They have had their hope & faith shattered too many times before. And if this legislation survives the inevitable political compromises and still remains armed, then this committee must take the next step which is to initiate the research necessary to create a cure for chloracne, which doesn't exist at this time.

In terms of S.1787 I must say that I have waited ten years to see legislation proposed which would compensate for non-Hodgkin's lymphoma, lung cancer and disabilities associated with suppression of the immune system. I whole heartedly support such a measure and I congratulate and thank you for it. However, the VA has demonstrated too many times in the past that they are incapable of gathering and/or analyzing data pertaining to Agent Orange Veterans.

(continued)

The Veterans have grown to mistrust the VA and I feel that the burdon of reporting disabilities that are compensable to Vietnam Veterans would be too much for that agency to handle. There is too much room for budgetary and political self-interests.

I notice, Senator, that this Committee is receiving testimony today from a newly formed Agent Orange group entitled the "National Assoc. of Agent Orange Survivors". I do not have to hear their testimony to know what they will say. I am saddened that they have to exist at all. However, I salute their courage & determination and offer what help I can give them. Their very existance demonstrates our nations failure to address the Agent Orange issue.

I am also angered that they will have to sacrifice their time, energy and money in order to help those suffering. In 1985 our organization did an accounting of the amount of money spent by the members of our organization and their families which comprised our 68 chapters throughout the nation. It totaled more than six million dollars. My point is, "Vietnam Veterans have had to pay out so much, for so long, for so little in return". Now this new group is forced to pay more.

Paul Reutershan, our deceased founder, Ed Juteau and Charley Hartz, our deceased vice-presidents, have given the ultimate sacrifice of their lives and they gave the little funds they had as well. Most of our official chapters had to close because of the extreme financial burden and I do not wish to see the same thing happen to this new group. They should not have to bear the governments responsibilities.

For more than a decade the Agent Orange issue has festered in the consciousness of America like an open wound. Much of the science & medicine is too complex and will never be known because the proper prospective and retrospective epidemiological studies will never be done. However, the most important questions pertaining to the Agent Orange issue can now be answered as a result of the Agent Orange law suit. The questions are; how many Vietnam Veterans claim to be damaged and how many claim that their children have been damaged? 249,000 Veterans and families and 64,000 children.

These numbers, these individuals are the Agent Orange issue. They have signed on the dotted line and made bonified claims to the Federal Court that they or their children have been damaged as a result of their exposure to Agent Orange. As you can see, the 64,000 claims for birth defects constitutes 40% of the issue. That means, Senator, that this government, for the last 10 years, has hardly even spoken about 40% of the Agent Orange issue and has helped not one single child or family. That, Sir, is a national disgrace and a moral outrage. We as Veterans have had enough of this unjust discrimination.

I want to know why this legislation and every other has failed to even mention these families, these children, this 40%? More importantly, when is this government going to start to address the castastrophic situations facing these children?

(continued)

Don't tell me the reason why this nation can not help these children is because we do not have the overwhelming conclusive evidence that their birth defects are a result of the Veterans exposure to Agent Orange. For that position is indefensible in that it matters not what caused the defects; what matters is that the children receive help.

Many of those 64,000 children have birth defects and/or disorders which are, in fact, repairable or reversable. However, those Veterans do not have the funds or the endurance to cover the costs of the surgical operations or medical treatment. Consequently, the children suffer with horrible facial, bodily or psychological injuries unnecessarily. That is unjustifyable, Senator, and legislation must be drawn up by this 100th Congress to address this catastrophic problem, today.

If the reason why these children are not being helped by the VA is because political powers of the left or right do not wish to change VA Title 38 to include, for the first time in our nations history, our children injured as a result of war than legislate the programs necessary to help these children through the Department of Health & Human Services. In other words, do not continue to do to us what the 2nd Circuit Court of Appeals did by denying our children the help because they did not want to set precedence. When precedence causes injustice and suffering I say to hell with precedence!

There is no justification, Senator, no logical, decent reason why this government can not help these children and families. Words can not express the extent of suffering being endured by these families. Four years ago our organization created the Brandie Schieb Fund to raise money to repair the facial defects of one of these children, Brandie Schieb. We have no problem raising the $100,000 to $300,000 it will take to pay for several surgical operations she will need untill her face stops growing at age 16. After two operations her face has changed so much that her classmates no longer make fun of her at school and her outlook on life has changed from a life of horror to a life with a bright future before her.

Brandie is the exception, the rule is that there are thousands more like her, each suffering similar problems but with the same lack of care or hope. Brandie's parents, Michele and Hank, out of their great concern for the other children, have helped us to extend the Fund to include the other 64,000. Today we help those children from coast to coast. However, I do not want to give you the impression that we are in any way capable of helping so many children with so many problems. That is why I need your help, Senator, and the help of every American who says that they care about Vietnmam Veterans.

For more than a decade the Agent Orange Veterans and their children have been lied to, cheated out of benefits, discriminated against, exploited, sensationalized, trivialized and experimented on by multitudes of medical hacks and insensitive scientists from the Veterans Administration to the Centers For Disease Control.

(continued)

For more than a decade not one study that has ever been completed anywhere in the world has concluded anything relevent to ending the suffering. More hundreds of millions of wasted funds!

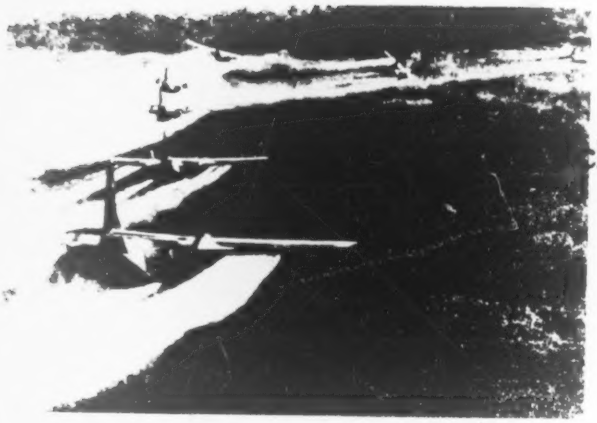
These sick, dying and injured Americans have literally given their body parts and their last moments of life for the cause - - so that no other human being will have the misfortune to be exposed to Agent Orange & Dioxin. They have opened their lives up to the cold scrutiny of the various medias, paraded before hundreds of city, county, state and federal government hearing rooms to give testimony and they have lived every waking moment of their lives for the last 20 to 25 years engulfed in the negative aspects of the Vietnam war.

As I stand before you and this committe today, Senator, I carry with me the hopes, dreams and desires of 64,000 children and their parents. They have kept faith in their nations judical system and have been slighted. They have kept faith in their nations legislative process and have been forgotten. Worse, they have been treated as merely the **" 64,000 dollar question "** - too costly to consider. They are crying out for intervention and understanding. They must be recognized and given the highest priority possible. To do otherwise is unconscionable.

In closing, Senator, I wish you and this Committee to know that I stand ready to provide you with any and all assistance necessay to address and end the suffering of our children. I would not dare to speak for Judge Weinstein except for his willingness to help the children. The responsibilty for everyone of the 249,000 Vietnam Veterans and especially the 64,000 children rests on your shoulders, Senator, and the shoulders of every American who sits in any position of authority in this nation. My breath is taken away at the thought of what could be done for our children if the Agent Orange Settlement Fund, the 100th Congress, the Brandie Schieb Children's Fund and the American public were to assist each other with the objective of ending the suffering.

Thank you.

Frank McCarthy,
President: Vietnam Veterans Agent Orange Victims, Inc.
Administrator: Brandie Schieb Children's Fund



hieb Children's Fund

205 Main Street
Stamford, CT 06901
Phone (203) 323-7478

FUND HISTORY & OBJECTIVES

More than 64,000 Vietnam Veterans and their families claim to have children born with birth defects which may have resulted from exposure to Agent Orange/dioxin. Some of the children have defects and disorders which are repairable and/or reversible.

However, many of the families are turned down for insurance coverage to pay the high cost of surgery or rehabilitation therapies. The Veterans Administration provides no medical help whatsoever for the Veteran's children. No other State or Federal government entity provides such help.

Accordingly, on March, 1985 Vietnam Veterans Agent Orange Victims, Inc. (VVAOVI) created the " Brandie Schieb Fund " in order to establish a mechanism for healing of these children and their Vietnam Veteran families. No longer would these children be caught in an economic or social void.

Brandie, the 7 year old child of Hank & Michele Schieb, has several facial defects which are repairable with the proper medical care and was the first child to benefit from the fund. Mr. & Mrs. Schieb wished the fund to be expanded for other children and families similarly situated.

Funds could now be generated to:

1) pay for medical operations
2) purchase orthopedic and/or therapeutic devices
3) provide food & clothing where necessary
4) pay for remedial programs

Donation of material items as well as funds are also collected for the children and under VVAOVI's non-profit charitable 501 (c)(3) status all items are tax-exempt.

This paper & printing was donated by Mr. John Nagle.

OTHER FACTORS!

Testicular cancer is RARE in middle aged and older men. However, other risk factors are:

1) If you have a family history of testicular cancer.
2) Male caucasians.
3) Men who have had viral infections or mumps which brought about atrophy of the testicles.
4) Men who had undescended testicles.

EXPLANATION OF TERMS

EPIDIDYMIS: *A soft, tube like structure on the back side of the testicles.*

TESTICLES: *Usually two egg shaped and somewhat firm organs located below the penis.*

SCROTUM: *A pouch of skin which holds the testicles.*

VIETNAM VETERANS
AGENT ORANGE VICTIMS, INC. (AOVI)

Design – Todd Neal • NYC

WHAT VIETNAM VETERANS SHOULD KNOW ABOUT TESTICULAR CANCER.

IT COULD SAVE YOUR LIFE!

This guide to Testicular Self-Examination is designed to provide you and your family with a step-by-step method of detecting abnormalities which could be Testicular Cancer. This guide will attempt to answer significant questions!

Veterans Administration (VA) and Department of Defense (DOD) records confirm the fact that most Vietnam veterans were exposed to various chemicals which scientific studies have shown to be highly carcinogenic. Agent Orange, Agent Blue and Dioxin are but a few. Swedish studies of Dioxin and exposed forest workers show a six fold increase in the risk of soft tissue sarcomas (cancer).

Regardless of whether you were exposed to these chemicals the fact remains—Testicular Cancer is the number one cancer killer in men of the same age group as the Vietnam veteran.

TESTICULAR SELF-EXAMINATION GUIDE

© Vietnam Veterans Agent Orange Victims, Inc. 1983 Frank McCarthy, President 27 Washington Square North, NY, NY 10011

WHAT IS TESTICULAR CANCER?

Testicular cancer is the most common cancer (solid tumor) in men between the ages of 15 & 40. It is also the number one cancer killer in men between the ages of 27 & 40, which is the average age of the Vietnam veteran. However, Testicular cancers are the most curable if they are detected and treated in their early stages before they can spread to other areas of the body. The most recommended method of detection is the TESTICULAR SELF-EXAMINATION!

The cancer itself is mostly confined to one testicle. The uneffected testicle will provide one with the capability of orgasm, erection, sexual fertility and a relatively normal life.

When a lump or tumor is found in one of the testicles it may not be cancerous. However, 96% of all tumors found in the testicles are cancerous. Most physicians agree that instead of removing the tumor the surgical removal of the testicle should be done in order to avoid the spread of the cancer. This, of course, depends upon the type of tumor and cancer.

Many patients have their testicular lymph nodes removed. After surgery, chemotherapy and radiation therapy are sometimes used and followup tests are conducted in order to check for the spread of the cancer.

WHEN SHOULD I CONDUCT A TESTICULAR SELF-EXAMINATION?

At least once a month. Make it part of your personal hygiene! The best time is during or just after a shower or bath. This is the time when the skin around the testicles is most relaxed.

WHY SHOULD I BOTHER?

Mostly, because it could save your life! The Self-Exam, done on a regular basis can greatly increase your chances of detecting abnormalities and testicular tumors and cancers.

Early detection of Testicular cancer makes it one of the most curable cancers. Without early detection, or, if you do not seek medical assistance immediately, it can be one of the most fatal cancers.

The Self-Examination will familiarize you with the normal consistency of your testicles so you are able to detect any abnormalities early.

WHAT ARE SOME OF THE SYMPTOMS OF TESTICULAR CANCER?

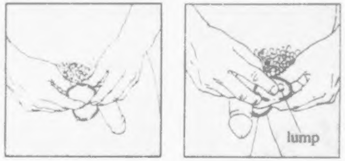
- Small painless lump on the testicles.
- Heavy feeling in the testicles.
- Dragging sensation in the groin.
- Pain could mean advanced cancer or other problems.

WHAT DO I DO IF I HAVE THESE SYMPTOMS?

See your physician immediately! These symptoms may not mean cancer! Many other problems in the male genitalia are confused with cancer. *See your doctor!* Only a physician can evaluate the abnormality. Do Not Panic, but, do not disregard the symptoms!

HOW TO CONDUCT THE TESTICULAR SELF-EXAMINATION.

While holding each testicle separately apply some pressure with the thumb and fingers of both hands.



If you see a lump or feel an area of firmness, stay calm, but, contact your physician immediately! If you do find anything abnormal most often it will be an area of firmness on the front or side of the testicles.

TESTICULAR CANCER AND YOUR MALE CHILD.

The testicles of a male child are formed near the kidneys. The testicles DESCEND to the scrotal sac approximately one month before birth.

However, a small percentage of children's testicles DO NOT DESCEND before one year of age. Testicular cancer is *40 times* more likely to occur in men whose testicles DO NOT DESCEND after they are 6 years old.

If you or your son have an UNDESCENDED TESTICLE contact your physician because a simple surgical technique can bring the testicle down into the scrotum and considerably DECREASE you or your child's chances of contracting testicular cancer.

ALAN CRANSTON
CHAIRMAN

United States Senate
COMMITTEE ON VETERANS' AFFAIRS
WASHINGTON, D.C. 20510
PHONE: 202-224-9126

January 31, 1980

To: Mr. Frank McCarthy

Please review and correct your remarks, supply any additional information or exhibits requested, and return to—

Hon. Alan Cranston, Chairman
Attn: Editorial Director
Committee on Veterans' Affairs
Room 414, Russell Office Building
Washington, D.C. 20510

I would appreciate having the transcript returned by—

February 11, 1980

Vietnam Vets Readjustment
Jan. 26, 1980 Los Angeles
Calif.

Sincerely,

ALAN CRANSTON,
Chairman.

GPO [illegible]

Chairman Cranston. Thank you very much. And I appreciate your brevity because we need to do that in order to cover everything.

Frank McCarthy, could you go next?

STATEMENT BY: FRANK MCCARTHY, PRESIDENT
AGENT ORANGE VICTIMS INTERNATIONAL
MOHEGAN LAKE, NEW YORK

Mr. McCarthy. Yes, Senator. My name is Frank McCarthy and I'm president of Agent Orange Victims International.

Agent Orange is a 50-50 mixture of two different types of herbicides that kill. My testimony here is to tell a story; it is to tell the story of the Vietnam veteran in conjunction with Agent Orange.

Senator, I want to make it perfectly clear that we do not blame the government for the problems brought about by Agent Orange. Dow Chemical Company lied to the Air Force and the Army. They exposed us to the most toxic substance known to mankind and now our children are being born with horrendous birth defects, our young men are dying of cancers that they shouldn't receive until their 50's or in their 60's, and the suffering for years and years and years is irreparable.

Earlier this morning, Senator, we met with Max Cleland. He promised us a full epidemiological study, a full epidemiological study. He promised us genetic testing for all the families of Vietnam veterans. He promised us treatment of Agent Orange victims. Senator, it simply does not exist. There is no treatment for us at this time. There are studies, there are people working in different areas, but we are in urgent need.

How the Air Force and the Army in one of the greatest countries that the world has ever known was ever lied to by five chemical companies is of great concern and we feel that it should be brought out to the public.

These chemical companies told the Air Force and the Army that the herbicide would land on the leaves and the stems of the plant; it would kill the plant. And then the sun would dissipate the dioxin within six to twenty-four hours. Now, this is true, if it stays on the leaves and stems of the plant. In Vietnam it did not; it rained every day, Senator, and it got into the waterways, it got into the food, it got everywhere. We are never ever going to be able to tell exactly who was exposed. We feel all Vietnam veterans were exposed.

Now, the reason why I say we are not going to be able to be told is because the Army records were destroyed. they were left in Vietnam. The only ones, as far as to our knowledge, that have any records are the Marines. So we can document the Marines.

However, it washed off the leaves and the stems of the plants. It got in the water. Here the Vietnam veteran -- we come along. We are not thinking about the herbicide. We are not thinking about drinking the water. We were told to put a couple of purification tablets into the water, shake up our canteen and drink it down. Now, dioxin has a long half-life in water, so that is how we got it; we drank the water, we breathed the air and we got it ingested within the pores of our skin.

The birth defects in our children have never been seen in medical science except in animal experiments with dioxin. We need no further proof. The proof is in our people.

Since 1970, after the government stopped the spraying of Vietnam, and, incidentally, stopped the spraying in our parks and recreational areas back here in the States, they have been spraying 9.2 million pounds of Agent Orange, 245T, along our railways, along our highways, under our power lines. So the civilian population is coming down with the same symptoms and effects as the Vietnam veteran, who have the same symptoms and effects as the Vietnamese people, who have the same symptoms and effects as the peoples in Chivasso, Italy, and Germany, Sweden, France, Holland. The evidence is overwhelming. The studies are necessary, however, we are constantly have to go around to prove that our suffering is caused by Agent Orange. Chloracne is only manifested through dioxin poisoning. Only two of our veterans in the whole nation have been compensated for only chloracne and 10% at that.

How could the VA, prior to this promise today by Max Cleland, sit there and testify before the Veterans Affairs Committee of the House that 2.4 million veterans were exposed and only two veterans got sick? All they got was chloracne? We don't buy that, Senator and we cannot buy that. We are the largest body of Agent Orange victims on the planet. Since we have done press around the country for the last two years, we have been inundated with letters from Australian Vietnam vets, New Zealand Vietnam vets, Korean Vietnam vets. They are suffering the same symptoms and effects.

Now, I've reached my limit, Senator. We brought this issue to the House, we brought it to the Senate, we brought it to the President of the United States personally, we brought it to the scientific community. We have reached out to humanity to help humanity, to help these veterans. We have no place else to turn. There is nowhere else for us to go. There is no one left to turn to. We have been watching our men die year after year. We need genetic counseling for the future generations.

We initiated a $10 million lawsuit against the chemical companies. It was amended into a major class action suit.

We are not asking to destroy the chemical companies. We don't want to put them out of business. We don't want thousands of people to be out of work. We want them to own up to what they did. We are asking the courts to award us a percentage of their profits to go into a trust fund, a public trust, administered by the courts and overseen by the world. And the money in that trust will be used to repair the damage done to our children, to compensate the men who have become disabled from it and to do the proper research necessary to create the treatment that does not exist at this time. No one can sit here and tell us that there is a cure for chloracne; there is none. That is why we initiated the class action suit against the chemical companies.

So, we are appealing. We are reaching out. We have no place else to turn, Senator. It is horrendous.

In 12 years of combat, 57,002 men were killed as a result of the war. Since 1974, over 51,207 veterans have died here in the States. That is shocking. These are men who put their lives on the line. They disregarded the political implications of the Vietnam War. They served their country, irregardless of whether it was right or wrong. If we all would have gone to Canada, we'd be speaking Russian today. We didn't go to Canada. We went and we fought in a war and we took our chances on a bullet and we fought for freedom, we fought for democracy, we fought for the American way. We fought for the same ideals as our fathers in World War II. And we come back and we ask for two things. We ask for medical treatment and an education. That is what we were told we were going to get. We did not get either and we are not getting it now. And now they are dying and they are going to be dying.

Max Cleland today said to everyone -- he said, "I don't want to scare 2.4 million Vietnam vets." He does not want to scare the American public. Well, we don't want to scare the American public either, Senator, but there are 2.4 million of us -- well, there are 2.8 million of us; they say 2.4 were exposed. We don't agree with that; we feel everyone is potentially at risk. But there are veterans out there who have cancer, Senator, and they don't know it. And they have a right to know that they were exposed to a carcinogen. And if we find those veterans, if we target them in time enough to detect their cancer at a treatable stage, we are saving lives.

Now, our organization -- we are in 17 different States. We are doing the job of the Veterans Administration. We are trying to provide services. We have been trying to do this for two years. We provide legal, medical, referral, counseling, support and outreach. We should not exist as an organization. We don't want to exist as an organization. We are doing the job of the VA.

I would love to be able to call all the branch offices and all the victims and say, "Our job is over. Go about your life and be happy." But we can't do that as long as veterans are dying everyday and as long as our children are being born with birth defects.

Since two years ago, we realized that the problem was much more extensive than the Vietnam veteran. It is not a Vietnam veteran's issue. It is a humanitarian issue, the civilians. So, we are fighting for you, Senator, because you are being exposed, the press is being exposed, the American civilian population, as well as the Vietnam veterans, are being exposed.

So, we are asking you, we are asking Congress, the Senate, the President, make sure that Max Cleland follows up on what he promised.

Thank you.

(Applause)

Chairman Cranston. Thank you very much. Thank you for a very eloquent and very heart-felt statement. It is a very strong one and I appreciate it deeply.

Are you going to go next, Mr. Gureckas?

Mr. Gureckas. I believe that Maureen Ryan was next.

Chairman Cranston. All right.

Go ahead.

organization as it relates to the Long Beach VA Medical Center. Some of that doesn't pertain to the direct responsibilities of this hearing, but it does relate to the responsibilities of the Committee itself and we will look into that, do what we can. I know there are questions on recruitment and retention of health care personnel that needs attention. We must do all we can to insure that there is adequate medical care for those who need help in the VA system and I will do my best, and am doing my best. And we've made some progress but still have a long way to go.

Mr. Gureckas. Thank you very much, Senator.

Chairman Cranston. Frank, do you have statistics on how many veterans appear to have the skin conditions which seem to be most directly, without much question, related to exposure to dioxin?

Mr. McCarthy. We are, at the present time, trying to put together our statistics and do a study ourselves of ourselves, Senator, and we have an initial telephone contact with the veteran and the majority of our veterans do say they have a rash of some sort.

Chairman Cranston. The majority of veterans?

Mr. McCarthy. The majority of all the veterans that call us from all parts of the country.

Chairman Cranston. Well, that is the majority that call you, not the majority of all veterans.

Mr. McCarthy. No. The majority that have contacted our office. We are speaking specifically of our --

Chairman Cranston. How many have you heard from up to now?

Mr. McCarthy. Over 8,000. The calls are coming in approximately 175 per day.

Chairman Cranston. You have over 8,000 that state they have a rash of some sort now?

Mr. McCarthy. No. As I said, we don't have those statistics yet, but we are trying to compile a -- you have got to understand, Senator, now, our 17 offices are being run by veterans who are either dying of Agent Orange or whose children are born with birth defects or veterans who are suffering in some way. We receive no financial support whatsoever from anyone anywhere. Each office is run out of the homes of the veterans and the office expenses and everything involved with this is taken out of their pockets.

Chairman Cranston. Yes, I understand that.

When do you expect you will have some statistics that would be significant?

Mr. McCarthy. Well, I think we are going to try to make them available to the courts and to the Senate and to the President within the next two months, I hope.

Chairman Cranston. Well, please do make them available to us as rapidly as you can.

Mr. McCarthy. They are coming in so fast, Senator.

Chairman Cranston. What kind of a breakdown will you have of that material? Will you, for example, have figures on how many cases you have established of the children of veterans who have deformities?

Mr. McCarthy. The birth defects, the type of birth defects, the cancers, type of cancers, neurological problems, the skin rash problems, the sexual dysfunction, the hearing loss, the psychological problems.

For the first time since the Bubonic Plague in this country, Senator, we have a massive population, the Vietnam veteran, who are suffering from abnormalities and disorders that cover the entire spectrum of chronic toxicity, carcinogicity, utergicity, tritogicity(ph); they're a legion among the Vietnam vets. And these abnormalities and disorders from different data banks that are available to the Senate and to the Congress and to the President and to the American public, to the press.

Chairman Cranston. But what information do you have on how many children have birth defects?

Mr. McCarthy. As I said, Senator, we have had no time to put together statistics. They're irrelevant to us at this point. The statistics around the world are overwhelming. Our plea has been to stop the deaths. You see, we not only receive Agent Orange calls, but we receive suicide calls. At least 1 out of every 9 or 10 calls is a suicide victim. We have a 27% higher suicide rate than the national average and the VA has no way -- you know, this psychological readjustment counseling, a whole program that Max Cleland has implemented is a joke to us. He testified before the Veterans' Affairs Committee of the House to get the money for that program by saying that they have 700,000 Vietnam vets in need of that program themselves to get that money. Now, he got that money but they're not using the veterans they have on record as needing that counseling. They got the money. They have broken it down into three teams in each individual location; there is, I think, 300 at the most counselors for 750,000 veterans on file and they are not appealing to them; they are not contacting them anymore than they are contacting Agent Orange victims. They are going to the streets. They want the vets to do the job for them again.

Chairman Cranston. I don't think that is all on file. That is basically an estimate at the present time. We do need the information and I think it is wonderful that you are doing what you can to help provide it.

Do you have any information from Vietnam as to how many people there are suffering the same?

Mr. McCarthy. Well, Dr. Tong(ph) just left the United States. He was recently here and he left a lot of statistics. We thought he had data, but he doesn't.

Chairman Cranston. What is your understanding of the use of dioxin presently inside this country?

Mr. McCarthy. Inside this country?

Chairman Cranston. Yes, now.

Mr. McCarthy. It's not very -- it's horrendous, I mean, to be perfectly straight out. Let's put it really on the table. Now, hexachlorophene, years ago -- do you know about hexachlorophene, Senator?

Chairman Cranston. Yes.

Mr. McCarthy. We used to brush our teeth with it, wash our clothes with it, wash our bodies with Dial Soap and Phisohex. That is the same material, same chemical, that was used in the Chivasso, Italy, plant that blew up and contaminated 45 square acres, never to be used again by humans in Chivasso, Italy.

Chairman Cranston. On the specific issue of dioxin, what is your understanding of its present use inside the United States?

Mr. McCarthy. The EPA has just banned, on March 2nd, 75% of the use. Now, it is still being sprayed on the rice crops and the ranchlands, so I don't eat rice anymore.

Ms. Ryan. Excuse me. I would just like to interject something when Frank said about all the rice crops. Presently, down in Arkansas, there is a plant by the name of Vertak which is leaking dioxin. They found it outside the plant in the bayous, in the creeks. And Arkansas is our shellfish, so that will give you an idea of the contamination.

Mr. McCarthy. To give you an indication of how free the chemical companies are in subjecting us to toxic substancies, if you will check with the EPA, they will tell you that the chemical companies can register a product with the EPA without having the EPA inspect, just by placing it under a category of nonmanufacturing. In other words, they are saying, "We want to register this product, but we are not going to manufacture it." Meanwhile, they will go to Conn Edison or one of the utility companies and say, "Well, there is a lot of bad press on this dioxin, so why don't you use this product?" Now, we don't know what that product is and they manufacture it and put it out. They have no controls. Dioxin is more toxic than plutonium and we have stringent controls over plutonium, but none over dioxin.

Chairman Cranston. Well, let me say that those of you who have testified have been very eloquent and forceful. I appreciate it very much. It is very helpful to us in our efforts to try to help deal with the problem. You've given us some new momentum and some new information, some new impetus and we will do our best to move swiftly to be of help. I know help is needed.

I thank you very, very much for your courage and your forcefulness and my staff will be in touch with some

Statement of Christopher Gregory to the United States Senate Committee on Veterans' Affairs

May 12, 1988

Mr. Chairman, distinguished members and friends,

I am Christopher Gregory from Massachusetts, a Vietnam veteran, who has administered my State's Agent Orange Research Program. In administering this program I saw first-hand the difficulties of conducting research into the health problems of Vietnam veterans, and the very tragic consequences of diseases caused by exposure to Herbacides. There are thousands of Vietnam veterans who are facing serious health problems in Massachusetts. They have come forth to volunteer for testing, seeking help for birth defects, and advice and consolation for their medical problems. Very soon after beginning to work on the problems of veterans who were exposed to herbacides I noticed that many of these men are sick. Their health problems are numerous, varied and often very serious. I know that an impression like this means little in a scientific way. But still the impression is so powerful and so frequently reinforced that it is impossible to dismiss.

If I may, I would like to pass on to you some of my experiences running a research program for the Commonwealth of Massachusetts where we produced significant results in three areas -- Posttraumatic Stress Disorder, Soft Tissue Sarcoma Mortality and Incidence -- in spite of the Veterans Administration's efforts to slow down and impair our research programs. First, I would like to inform the Committee that one of the members of the Veterans Advisory Committee on Environmental Hazards is in a conflict of interest. Dr. Theodore Colton of Boston University, a prominent academic, served on the Advisory Committee and was at the same time serving as a paid advisor to a law firm representing Monsanto Corporation in a legal action brought by chemical workers who had been exposed to dioxin in Nitro, West Virginia. Fredric L. Conway, Executive Secretary for the Veterans Advisory Committee, acknowledged these facts in correspondence with me in 1985, in answer to my letter informing them of Dr. Colton's apparent conflict. Mr. Conway wrote to assure me that Dr. Colton's position was fully understood and his situation "discussed with the present and former General Counsel of the Veterans Administration and with the Agency's ethics official" and that they, after due consideration, found no conflict of interest. I find it hard to agree with their decision, in light of the fact Dr. Colton was on the payroll of Monsanto while he was involved in promulgating regulations to compensate for injuries caused by exposure of Agent Orange -- a Monsanto product. It seems clear to me that Dr. Colton was indeed in conflict of interest and that the regulations he participated in formulating are tainted as a result.

In spite of the archly-political atmosphere that has been created by the Veterans Administration on the Agent Orange issue, we in the Commonwealth of Massachusetts are especially proud of three studies that we completed that show concrete relationships between service in Vietnam and both physical and mental disorders.

I would like to speak first about findings where a statistical connection between service in Vietnam and Soft Tissue Sarcomas, a type of cancer. Richard Clapp of the Massachusetts Department of Public Health, with Michael Kogan, conducted our study "Soft Tissue Sarcoma Mortality Among Vietnam Veterans in Massachusetts 1972 to 1983," which was published this spring in the International Journal of Epidemiology. In

Massachusetts all cancer diagnoses are reported to the State's Cancer Registry for statistical analysis, of which Mr. Clapp is the director. It was in this capacity that he was able to document the correlation between service in Vietnam and a high incidence of soft tissue sarcoma mortality. All hospitals, except some of the V.A. hospitals, cooperated with this effort, which, although it did not completely thwart the research did make it more difficult. The V.A.'s refusal to cooperate raises very serious questions about the V.A.'s interest in discovering information about veterans' health problems. Why would the V.A. decline to give information on two separate occasions?

The statistics generated by our studies of soft tissue sarcoma mortality among Vietnam veterans, as opposed to veterans of the same era who did not go to Vietnam, show mortality nine times more likely for Vietnam Veterans. The study of incidence of soft tissue sarcoma in the same two groups shows that Vietnam veterans are five and a half times more likely to have Soft Tissue Sarcoma than other veterans. I have reprints of the studies with me for anyone who wishes to have them.

In another Massachusetts study by Charles J. Levy on Agent Orange, published this spring in the Journal of Nervous and Mental Disease, we have found a demonstrable connection between herbacide exposure and Posttraumatic Stress Disorder. The V.A., which afterall has the most complete information on the individual health problems of veterans, was again uncooperative with this research effort. This study was especially interesting because it looked at chloracne, the one specific medical indicator of exposure to the dioxin in Agent Orange and other herbacides. Chloracne is a compensable disorder under existing V.A. regulations, but not one case of chloracne is acknowledged by the V.A. among Vietnam veterans in New England. Dr. Levy of Harvard Medical School and McLean

Hospital was able to locate 42 cases that were indicative of chloracne and six currently active cases, all in just the greater Boston area. As chloracne is the reliable indicator of dioxin exposure you would expect the V.A. would actively search out veterans with this disorder. The reverse is true, they discourage recognition of this disease and when contacted by Dr. Levy in the course of his research, an administrator refused to discuss the possibility of any cases of chloracne exisitng in our state.

These three studies raise some very compelling questions about disease among Vietnam veterans, but they have broader implications as well. How is it that we in Massachusetts, with a relatively small amount of money, can locate and prove relationships between Vietnam service and disease when the V.A. with budget responsibility for $25 billion, can find almost nothing? And why has the V.A. withheld information that might be valuable for research purposes?

I believe enough evidence exists from studies in my state and elsewhere to justify a presumption for Vietnam veterans who have a disease associated with herbacide exposure. I urge the committee to amend this bill to include other diseases and to report the final version out favorably. The effect of this action will lessen the suffering and worry of many many sick veterans.

Thank you.

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Agent Orange Exposure and Posttraumatic Stress Disorder

CHARLES J. LEVY, PH.D.[1]

Evidence of organic psychological deficits in Vietnam veterans exposed to the herbicide Agent Orange was established through a neuropsychological battery. Also, the exposed Vietnam veterans, in contrast to a matched control group of Vietnam veterans, showed a significantly higher rate of posttraumatic stress disorder and its associated features: depression, anxiety, and increased aggression. The latter was subdivided into uncontrollable pressures, verbal violence, violence against objects, assaults, and suicidal thoughts. Active cases of chloracne, a medical indicator, were used to determine Agent Orange exposure.

Industrial workers who have been exposed to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) present psychological symptoms (Bauer et al., 1961; Office of Science and Technology, 1971; Oliver, 1975) that duplicate those that have been attributed to the delayed effects of combat stress in Vietnam veterans (Figley, 1978; Levy, 1974; Sonnenberg et al., 1985). The present study explores the possibility that TCDD, the exceedingly toxic component of the herbicide Agent Orange, plays a part in these symptoms when they occur in Vietnam veterans who have been exposed to it. Agent Orange was sprayed extensively in Vietnam as a means of destroying cover and crops that might otherwise be used by opposing forces.

The following disorders are symptomatic of both TCDD-exposed industrial workers and Vietnam veterans with posttraumatic stress disorder (PTSD): memory impairment, trouble concentrating, constricted affect, and sleep disturbance (American Psychiatric Association [APA], 1980). Depression, anxiety, and increased irritability, at times resulting in violence, all associated features of PTSD, are also shared by the two groups. The fundamental reported difference between these groups is the etiology of the symptoms: organic brain damage has been found in workers who were exposed to TCDD (Bauer et al., 1961).

The following will be examined in this paper: a) whether there is a psychological deficit among Vietnam veterans exposed to Agent Orange, in contrast to a control group of Vietnam veterans, and b) whether the rate of PTSD and its associated features is higher in the exposed group.

Methods

Medical Indicator

Exposure to TCDD was determined by chloracne, "the most constant sign of [TCDD] intoxication" (Pazderova-Vejlupkova and Lukas, 1981). Chloracne is solely the result of exposure to aromatic chlorinated hydrocarbons (Crow, 1970) such as the TCDD contaminant of Agent Orange. The distinctive features of chloracne are a cyst ranging from 1 mm to 1 cm in diameter and comedones that can vary from a few to confluent sheets. In mild cases the lesions occur in the malar area, the jaws, and behind the ears; in severe cases, inflammatory papules and pustules may occur in areas in which there is friction from clothing (Crow, 1970).

Sample Selection

A population was derived from the list of veterans who received Commonwealth of Massachusetts bonuses as a result of serving in Vietnam. We concentrated on veterans living in the Greater Boston area. All of those veterans who could be located, a total of 1957, were initially interviewed on the telephone regarding skin lesions. Of these veterans, 42 subjects reported a condition that was possibly indicative of chloracne. They were subsequently examined. Of these, six had current mild cases of chloracne in the malar and postauricular areas.

Twenty-five control subjects were then randomly selected from the same bonus list. They had no signs of chloracne, through either an active case or scarring, nor did they have any recollections of chloracne symptoms. (Because of the widespread use of Agent Orange in Vietnam, it would have been difficult for a large proportion of combatants to avoid at least a slight degree of exposure, but our focus was on exposure for

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which there is a medical indicator.) The control subjects were matched to the exposed subjects on age (range 36 to 42), education (grades 10 to 14), and time of service in Vietnam (between 1964 and 1970, the period of Agent Orange spraying). Also, none of the subjects had held jobs that involved working with herbicides.

In order to control for the effect of combat stress, all of the control subjects had to meet a standard that equaled or exceeded the combat experience of the exposed subjects, a minimum of two contacts with the enemy for each of four successive weeks. Reports of combat experience were verified.

Data Gathering

A neuropsychological battery, selected for sensitivity to nonfocal effects of brain dysfunction, was administered to the exposed and the control subjects: WAIS Vocabulary Subtest, Rey Auditory Verbal Test (five-trial total, list A Immediate Recall, list A Recognition Score, list A Delayed Recall, List B), the Symbol Digit Modalities Test in written and oral versions, and the Word Fluency Test.

In addition, standardized interviews were administered to all subjects to determine whether they had, during the past 6 months, the symptoms of PTSD and its associated features: depression, anxiety, and aggressiveness. The interview schedule was derived from converting the DSM-III formulation of PTSD symptoms into questions. However, the DSM-III wording was altered whenever necessary so that it would be universally intelligible. For example, "exaggerated startle response" (APA, 1980) became "Have you reacted quickly when encountering an unexpected noise or smell that reminded you of Vietnam?"

Given the breadth of the aggressiveness category and the variations within it that we observed during an earlier study of Vietnam veterans (Levy, 1974), we subdivided aggressiveness into five components: uncontrollable pressures, verbal violence, violence against objects, assaults, and suicidal thoughts. The frequency of these aggressive incidents during the 6-month period, as reported by the subjects, appears under the relevant headings of PTSD Measures in Table 1.

The testers and interviewers were blind to the chloracne diagnoses of the subjects. Also, none of the subjects was given any indication during the course of the study that they were considered exposed. In fact, no reference to Agent Orange or chloracne was made when explaining the study. However, all testing and interview procedures were fully explained, after which informed consent of the subjects was obtained.

The means, standard deviations, and results from the one-way analysis of variance (ANOVA) were calculated comparing the average scores of the exposed subjects with those of the control subjects.

The correlations between the neuropsychological tests and the PTSD measures were computed using the Pearson's product-moment correlation.

Results

Quantitative Findings

As presented in Table 1, the exposed group scored significantly lower than the control group on six of the nine neuropsychological tests for brain dysfunction ($p < .05$, $df = 1,29$), four of which are highly significant ($p < .01$, $df = 1,29$). One other measure is approaching significance ($p = .08$, $df = 1,29$). The exposed subjects had significantly higher scores ($p < .01$, $df = 1,29$)

TABLE 1

Summary of Parametric Statistics Comparing All Variables in Exposed and Control Subjects[a]

Variables	Exposed[b] (N = 6)	Control[b] (N = 25)	F[c]	p[c]
Neuropsychological tests				
WAIS Vocabulary	56.33 ± 14.25	62.16 ± 9.76	10.64	.003
Ray 5-trial total	35.50 ± 4.67	49.12 ± 7.88	8.13	.006
Ray-Immediate Recall	7.50 ± 3.06	9.96 ± 3.01	3.21	.084
Ray-Recognition	11.00 ± 3.16	13.28 ± 1.62	.10	.757
Ray-Delayed Recall	8.33 ± 3.72	10.56 ± 3.17	2.53	.146
Ray-List B	3.67 ± 1.03	6.46 ± 1.92	4.93	.034
Symbol Digit/written	37.83 ± 10.11	55.12 ± 10.76	12.71	.001
Symbol Digit/oral	44.17 ± 10.91	57.52 ± 12.02	7.16	.012
Word Fluency Test	35.67 ± 7.06	52.44 ± 10.84	12.85	.001
PTSD measures				
Classification	1.00 ± .00	.20 ± .41	22.45	.000
Symptoms	10.83 ± 1.34	2.68 ± 3.36	34.26	.000
Associated features	1.00 ± .00	.96 ± 1.13	15.86	.000
Pressures	31.17 ± 34.57	1.20 ± 2.72	20.47	.000
Verbal violence	81.17 ± 113.75	3.56 ± 4.85	12.95	.001
Object violence	11.50 ± 19.04	.24 ± .60	9.76	.004
Assaults	5.17 ± 7.55	.12 ± .44	12.34	.001
Suicidal thoughts	1.67 ± 1.84	.00 ± .00	26.05	.000

[a] F statistics and associated p-values are from one-way ANOVAs of exposed vs. control means.
[b] Values represent mean ± SD.
[c] $df = 1,29$.

than did the control subjects on the measures for PTSD (Table 1).

Of the correlations between the neuropsychological measures (lower scores indicate greater deficits) and the PTSD measures (higher scores indicate more incidents), 92% are negative, which is as expected if there is a relationship between the measures. Of the correlation coefficients, 54% reach significance by one-tailed tests ($p < .05$, $df = 29$). (Nonparametric statistical methods produced results that in all cases parallel those of the parametric approaches.)

All of the exposed subjects met the diagnostic criteria for both PTSD and the three associated features (depression, anxiety, and aggression), in contrast to the control subjects for whom the PTSD rate was 20% and the rate for the three associated features was 8%.

Qualitative Findings

There were qualitative as well as quantitative differences between the two groups in the categories that we used to define aggressive behavior. DSM-III states that the aggressive behavior associated with PTSD occurs "upon even minimal or no provocation" (APA, 1980). This characterization applies to all of the exposed veterans. Subjects who reported uncontrollable pressures were asked, "What led up to it?" The following is a representative response from the exposed group:

> The top of my head feels like it's going to come off and like I'm trying to grasp something that's not there. I get all confused. . . . Any little thing just ticks me off. . . . I get aggravated very easy. I could wake up angry. . . . I don't know that these things happen until they were already going on.

In contrast to the vague and slight provocations of the exposed subjects, four of the five control subjects reporting pressures described provocations that were precise and substantial, for example, "When I was working on my house, and I needed some material, and didn't have the money, and bills were piling up." All of the exposed subjects and none of the control subjects reported that their susceptibility to pressures during the past year was greater than at any other period since their return from Vietnam. None of the exposed subjects and two of the control subjects experienced pressures before serving in Vietnam.

Discussion

Hypothesis and Null Hypothesis

The statistical evidence for organic psychological deficits in the exposed subjects is very strong, based on the results of the neuropsychological battery.

It is also clear that there is a very strong difference between the exposed subjects and control subjects on all of the PTSD measures, including the associated features and the components of aggression.

Further, there are enough significant correlations between the PTSD and neuropsychological measures to make it unlikely that this degree of association could occur by chance.

The null hypothesis that PTSD is solely responsible for the poor performance of the exposed subjects on the neuropsychological tests was rejected. One-way ANOVAs were computed for the control subjects and were grouped according to presence or absence of PTSD. This analysis was unable to detect a degree of difference between the groups on any of these nine neuropsychological measures sufficient to reach the .05 level. The average levels within the two groups were similar for most variables. Only two measures approached significant difference, and neither of these measures was among the ones that show evidence of significant relationship to the presence or absence of exposure.

Further, exposure appears to increase the prevalence of PTSD. The probability of finding six PTSD cases in six subjects in the exposed sample, based on the prevalence of PTSD among the controls (five of 25), is .000064 (*i.e.*, $.20^6$), which also leads to rejection of the null hypothesis.

The level of combat experience cannot explain the difference in PTSD scores between the exposed and control groups. Two of the exposed subjects experienced light combat, as compared with heavy combat for all of the control subjects. Nonetheless, of the 14 possible PTSD symptoms, the two exposed subjects with light combat experience had an average of nine symptoms. This was lower than the average of 11.8 symptoms for the four exposed subjects with heavy combat experience, but it exceeded the average of 7.8 symptoms for the five control subjects who had PTSD.

Minimization of Exposed Sample Size

For several reasons, the small number of exposed cases in this study may reflect a bias toward underestimation of the actual number of Vietnam veterans who were exposed:

1. As a conservative measure, only current cases of chloracne were included, but chloracne may consist of just a few comedones that clear a few months after contact. In approximately 80% of the cases, chloracne does not persist after 3 years (Crow, 1982). (The present study was conducted 16 to 22 years after potential exposure in Vietnam.)

2. Although chloracne is an indicator of *TCDD* exposure, the symptoms of exposure can occur without chloracne (Hoffman et al., 1986; Oliver, 1975).

3. Unless veterans acknowledged relevant skin le-

sions during the initial screening, they could not be considered for possible inclusion in the exposed category. There were indications of a reluctance to acknowledge skin lesions (especially comedones because of the lingering connotations they appeared to have with adolescent uncleanliness).

4. The bonus list from which these veterans are drawn is limited to those who were honorably discharged. If the exposure-induced aggression occurred before discharge, there is a greater likelihood of episodes that would result in less-than-honorable discharges.

5. If exposed veterans are more likely to place themselves in violent situations, and are more likely to contemplate suicide, a disproportionate number of them may have died due to violence committed by others or themselves.

6. The rate of violent behavior engaged in by exposed veterans suggests that a disproportionate number of them may be incarcerated and were therefore unavailable for the initial screening.

The low threshold for aggression among the exposed veterans has not resulted in incarceration, with one exception, at least in part because of the coping mechanisms they have developed for minimizing the danger to others from their violence (these mechanisms were not reported by the control subjects). Among their strategies is selecting jobs at which they are least likely to do violence because contact with others is minimal.

Violence against objects is another coping mechanism that appeared throughout our interviews with the exposed veterans. The following is characteristic of both the rage and the effort to redirect it:

> Whenever there's pressure on, I feel I can come close to doing anything. If somebody pisses me off and I'm getting wacky, I hit the walls and not them. I damn near went through both walls, and I was looking at somebody in the eye when I did that. I was talking to somebody then, I forgot what they said to me, but it really pissed me off, and I hit the wall. If I had hit them, I would've killed them.

The aggression of all the exposed subjects has put them close to the line of law violations. The one who crossed over it was imprisoned for stabbing two people, and he acknowledges a third stabbing. He has managed to alter the manner in which his violence is expressed: "I won't carry a weapon 'cause I know I'll use it." Veterans who were less successful in redirecting this violence would not have been in the sample.

Conclusion

Although we can only speculate on the actual number of exposed veterans, what we have found is that, when these subjects are identified, PTSD and its associated features could have a masking effect. That is, among the Vietnam veterans who most convincingly meet the diagnostic criteria of PTSD, there are those whose condition cannot be explained by combat stress alone. Therefore, the possibility of Agent Orange exposure should be explored when Vietnam veterans meet the diagnostic criteria of PTSD. Only in this way can the etiology of the PTSD symptoms be adequately established.

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Richard Clapp, Massachusetts Department of Public Health

SOFT TISSUE SARCOMA INCIDENCE IN MASSACHUSETTS VIETNAM VETERANS, 1982-1986

This investigation followed up previously published findings of increased soft tissue sarcoma mortality in Massachusetts Vietnam Veterans in 1972-1983. A computerized veterans file, which distinguishes Massachusetts residents paid a bonus for having served in Vietnam from those who were in the service at the same time but did not go to Vietnam, was linked to the Massachusetts Cancer Registry incidence file. Initial frequencies were 113 cases of cancer of all types in Vietnam bonus recipients and 477 cases of cancer of all types in Vietnam-era veterans; of these, 13 cases were reported as soft tissue sarcomas - 6 in Vietnam bonus recipients and 7 in Vietnam-era veterans. Subsequent verification of the diagnosis revealed three cases of Kaposi's Sarcoma coincident with AIDS - 1 in a Vietnam bonus recipient and 2 in Vietnam-era veterans. An additional reported case of spindle cell sarcoma was determined to have been benign and not reportable. Occupational information on military discharge papers and on cancer incidence reporting forms was uninformative.

Excluding the Kaposi's Sarcoma cases, all non-Hodgkin's Lymphoma cases, and the benign sarcoma, the crude odds ratio for Vietnam bonus recipients with the diagnosis of soft tissue sarcoma was 5.52 (95% C.I.= 1.46-20.92). Further data and follow-up work will be presented.

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Soft Tissue Sarcoma Mortality Among Vietnam Veterans in Massachusetts, 1972 to 1983

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Kogan M D (Massachusetts Department of Public Health, Cancer Registry, 150 Tremont Street, Boston, MA 02111, USA) and Clapp R W. Soft tissue sarcoma mortality among Vietnam veterans in Massachusetts, 1972 to 1983. *International Journal of Epidemiology* 1988, 17: 39–43.
Information from death certificates and veterans' bonuses identified 840 Vietnam veterans and 2515 Vietnam-era veterans who died in Massachusetts during 1972–1983. Causes of death among Vietnam veterans were compared to Vietnam-era veterans and other male decedents. Standardized PMRs and MORs were both elevated for soft tissue sarcoma compared to Vietnam-era veterans [sPMR = 880, sMOR = 5.16, 95% CI = (2.4, 11.1)]; as well as non-veteran males.

The Agent Orange Program in the Office of the Commissioner of Veterans Services (OCVS) requested that a mortality study be conducted comparing the causes of death occurring in 1972–83 among Massachusetts residents who were Vietnam veterans, Vietnam-era veterans who did not serve in Vietnam, and non-veteran males. The Agent Orange Program was established by the Massachusetts Legislature in 1983 for the purpose of supporting studies of possible health effects among Massachusetts Vietnam veterans. It has a Medical/Scientific Advisory Board, comprised of medical and behavioural scientists, who recommend and oversee the research activities supported by Program funds. The mortality study was motivated primarily by a concern that Vietnam veterans may be at increased risk of dying from violent, preventable causes such as motor vehicle accidents, homicide, and suicide.[1] Secondarily, other causes of mortality were investigated.

Because of the age distribution of Vietnam veterans, it was unlikely that diseases of old age or causes of death such as certain cancers would have occurred in sufficient numbers to analyse. In order to focus on relatively stable findings, only specific causes of death for which there were at least seven Vietnam veteran decedents were summarized. In the process of the investigation, two rare causes were estimated to be excessive among Vietnam veterans relative to veterans who had never served in Vietnam. Noteworthy among these was connective tissue cancer. This report examines the evidence for the association between location of military service and mortality due to several types of cancer. The findings concerning the relationship between violent preventable deaths and military service are discussed elsewhere.[2]

METHODS

In August 1984, the study was initiated using the computerized file of Massachusetts mortality data available from the Division of Health Statistics and Research of the Massachusetts Department of Public Health (MDPH). The mortality data for honourably discharged Massachusetts Vietnam and non-Vietnam veterans were obtained by linking the statewide computerized mortality files with the computerized list of veterans who applied for a military service bonus, available from the Massachusetts OCVS. It has been estimated that 90–95% of all eligible Massachusetts veterans received the bonus after presenting proof of military service of at least six months during the time period 1958 to 1973. (Personal Communication, Robert Feeney, Massachusetts Military Archivist, 1985.)

The mortality and veterans files were linked by matching social security numbers for the years 1972–76 and 1980–83. For the years 1977–79, social security numbers were not entered on the MDPH computerized files, although they continued to be recorded on death certificates. For these three years, the computer files were linked by matching names. The resulting output was then verified by hand-checking social security numbers on death certificates with the numbers from the veterans file.

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The computer linkage provided information on age at death, sex, race, cause of death, year of death, and service in Vietnam. Underlying cause of death was classified according to the appropriate revisions of the International Classification of Diseases and converted to the Ninth Revision codes.[3]

Because white males accounted for about 98% of the veteran decedents, and the non-white male population of Massachusetts was about 2% in 1970, cause of death data for non-whites or female veterans was very sparse. This report, therefore, is restricted to an analysis of white male mortality patterns, although information on other groups should be pursued in further studies.

The number of observed deaths from specific causes among Vietnam veterans was compared with the expected number of deaths based upon the actual mortality experience of both non-Vietnam veterans and all other males in Massachusetts. Veteran deaths were not included in the Massachusetts white male comparison group. The expected numbers were derived from calculations of age-time-cause-specific proportionate mortality within ten-year age groups. The ratios of observed to expected numbers of deaths were summarized using the standardized proportionate mortality ratio (sPMR).[4] This method was chosen because it is familiar to many and appears often in the occupational health literature. The statistical significance of the differences was assessed using the Mantel-Haenszel Chi-square test with one degree of freedom.[5] Confidence intervals of the sPMR were based on the results of the Chi-square tests.

For causes of death for which the sPMR was statistically significant, the standardized mortality odds ratio (sMOR) was also calculated according to the method described by Miettinen.[6] The sMOR was used to confirm the results of, and as an adjunct to, the sPMR method. The sMOR compares the odds for the exposed population—the number of deaths from the cause of interest compared with the number of deaths from selected reference (auxiliary) causes—with the expected odds derived from a comparison (non-exposed) population. The sMOR approach is essentially equivalent to the case-control approach, in which cases are all deaths from the disease of interest, controls are all deaths from the auxiliary causes, and the exposure of interest is service in Vietnam. The sMOR was also adjusted for age and year of death.

The sMOR has certain advantages relative to the sPMR. When the auxiliary cause(s) of death is unrelated to the exposure, the mortality odds ratio is interpretable as the observed-to-expected ratio. When standardized for age and time, the mortality odds ratio becomes the standardized mortality odds ratio and the observed-to-expected ratio becomes the standardized mortality ratio. In contrast, the sPMR can be quantitatively interpreted as the standardized mortality ratio only when the sum of the mortality rate(s) of interest and the rate for auxiliary cause(s) of death is the same for both the exposed and non-exposed.

The sMOR analysis was carried out using all circulatory disease (including cerebrovascular disease), except rheumatic heart disease (ICDA 390–459), as the auxiliary cause. All circulatory disease was chosen on the assumption that it was unrelated to the exposure of interest (service in Vietnam). Comparing Vietnam and non-Vietnam veterans to other males for circulatory disease, we calculated an sPMR of 93 and 95 respectively; this was not significantly lower than expected. Rheumatic heart disease is related to the exposure of interest because young men with the disease would presumably fail to pass their military induction physical exam.

RESULTS

Table 1 presents the results of the sPMR analysis, comparing Vietnam veterans to non-Vietnam veterans and to all other non-veteran Massachusetts males for specified causes of death. The sPMRs and their 95% confidence intervals are included in the table. Uncommon causes of death for Vietnam veterans are not presented because statistically stable comparisons could not be made. A minimum of seven observed Vietnam veteran deaths was used as a criterion for calculating an sPMR. Two methods of accounting for suicide deaths are used. The first method includes only those deaths that were recorded as suicides on death certificates. It has been estimated, however, that the actual suicide rate is three times the reported rate.[7] Therefore, a second calculation, known as an "estimated suicide rate," was carried out which includes all poisonings (ICDA codes E850-E869, E980-E982), recorded suicides (ICDA codes E950-E958), and unknown causes of deaths (ICDA code 799.9).[8] The analyses presented were carried out on 766 deaths from specific causes out of the total 840 deaths in the Vietnam veterans group.

The sMOR was computed for each cause of death for which the sPMR was statistically significant in either of the two comparison groups. The sMOR findings differed from the sPMR findings in only two instances: Homicide was not found to be significantly lower for Vietnam veterans compared to the state's non-veteran males (sMOR = 0.82), and motor vehicle

TABLE 1 *Standardized proportionate mortality ratios for selected causes of death for Vietnam veterans compared with either non-Vietnam veterans or non-veteran males*

ICD No.*	Cause of death	Observed Vietnam veteran deaths	Comparison group			
			Non-Vietnam veterans		Non-veteran males	
			PMR	95% CI	PMR	95% CI
	All Causes	840				
140-239	All Neoplasms	120	95	(78,115)	112	(94,134)
153-154	Colorectal	9	113	(56,226)	85	(42,172)
162	Lung, Bronchus	25	98	(66,146)	102	(72,145)
171	Connective and other soft tissue	9	880	(513,1510)	473	(262,855)
189	Kidney	9	183	(96,346)	353	(191,651)
390-429 439-459	Circulatory system (except cerebrovascular)	139	88	(75,103)	87	(74,102)
430-438	Cerebrovascular disease	28	111	(77,160)	138	(96,199)
571	Cirrhosis of the liver	29	94	(65,136)	90	(61,132)
E800-E999	All external causes	426	108	(98,119)	113	(103,124)
E810-E825	Motor vehicle accidents	200	110	(95,127)	127	(106,152)
E950-E958	Recorded suicides	142	93	(77,112)	118	(98,143)
(799.9, E850-E869, E950-E958, E980-E982)	Estimated suicides**	163	113	(96,132)	140	(120,163)
E960-E969	Homicides	31	80	(56,114)	66	(46,94)

* International Classification of Diseases, 9th Revision, code number

** See reference 8 for discussion of this category. Note that there were 13 deaths in the category 799.9

accidents were elevated for Vietnam veterans compared to non-Vietnam veterans only in the sMOR analysis (sMOR = 1.50).

DISCUSSION

Since this is a death certificate study, which utilized record-linkage techniques to assemble the study group, there are a number of potential limitations which should be taken into account when considering the findings. Among them are the following:

- The accuracy of cause of death information on death certificates has been about 90% overall and as low as 50% for certain malignancies compared to autopsy findings.[9]
- There is no information on death certificates concerning potential confounding factors such as smoking habits or socioeconomic status.
- Computer file-linking may miss potential cases due to erroneous recording of information on the variable that is matched on, such as social security number or date of birth.[10]
- Only honourably discharged veterans were used in the study, which limits the generalizability to that group. The percentage of Massachusetts veterans not honourably discharged is unknown but is probably less than 10%.
- The standardized proportionate mortality ratio is less easily interpretable for more common causes of death, such as circulatory system diseases.[4]

TABLE 2 *Mortality odds ratios for selected causes of death for Vietnam veterans compared with either non-Vietnam veterans or non-veteran males*

Cause of death	Comparison group			
	Non-Vietnam veterans		Non-veteran males	
	Mortality odds ratio	95% CI	Mortality odds ratio	95% CI
Connective and other soft tissue cancer	5.16	(2.39,11.14)	5.87	(2.92,11.78)
Kidney cancer	1.34	(0.99,1.80)	4.04	(2.12,7.67)
External causes	1.14	(0.95,1.37)	1.44	(1.08,1.91)
Motor vehicle accidents	1.50	(1.20,1.87)	1.65	(1.28,2.12)
Recorded suicides	1.24	(0.98,1.56)	1.46	(1.02,2.08)
Estimated suicides	1.48	(0.90,2.37)	1.73	(1.22,2.44)
Homicide	0.76	(0.24,2.39)	0.82	(0.64,1.04)

- Age-adjusted death rates could not be calculated because the ages of all the living veterans could not be obtained from the computer files.

The findings of this study are unlikely to result from the above limitations. There is no reason to suspect that Vietnam veterans were misclassified differentially from the other two groups. This applies both to misclassification of the file-linking information and the cause of death information. The bonus response rate for honourably discharged veterans was high (90–95%), thus limiting non-response as a possible cause of significant bias. The per cent of Massachusetts veterans not honourably discharged is unknown. It is possible that they may have differed significantly from the honourably discharged group. Missing information on potential confounders, on the other hand, might have caused a detectable effect, although not large enough to account for the observed differences for some findings. Given what is known about risk factors for connective and other soft-tissue cancer, it is unlikely that factors not examined accounted for all the excess in Vietnam veterans.[11]

In the interpretation of the findings, it is necessary to keep two other considerations in mind. First, the study group of Vietnam veterans was assembled from a list of Massachusetts residents who received a bonus after they had presented proof of service in Vietnam and honourable discharge. No information about length of service (beyond the six-month required minimum), precise location of service, or specific exposures to toxic substances, such as Agent Orange, was available from these records. Furthermore, no correction was made for possible social class differences between the Vietnam veterans and the two comparison groups. However, the Vietnam veterans findings for three causes of death which are highly correlated with social class—lung cancer, colorectal cancer, and cirrhosis of the liver—did not, in this instance, differ significantly from those of the comparison groups.

No significant differences were found between Vietnam veterans and the two comparison groups with respect to death due to malignant neoplasms as a whole. The significant elevation of malignancies of connective and other soft tissue (ICD 171) was based on only nine deaths; all of these were sarcomas of five different types. Pathological confirmation was obtained from hospital records or the physician in eight of these cases. Table 3 lists the nine cases by years of service, year of death and histological type. Occupational exposure as inferred from the limited information on the death certificate did not seem to be significant.

Two case-control studies from Sweden reported that soft-tissue sarcomas were associated with occupational exposure to phenoxyacetic acids such as 2,4-D and 2,4,5,-T, the components of Agent Orange.[12,13] One ongoing study of Air Force personnel engaged in spraying Agent Orange (Operation Ranch Hand) has found no deaths from soft tissue cancer; however, this study is focused on 1241 men who flew spraying missions between 1962 and 1971 and only 39 deaths have occurred which were summarized in a 1983 report.[14] A New York State Department of Health study reported no excess of soft tissue sarcomas after service in Vietnam. This study looked at both incidence and mortality for this cancer in New York (excluding New York City) diagnosed from 1962 through 1980.[15] It suffers from the fact that the latency period for the development of most cancers may be longer than the observation period of the New York study. The deaths observed in the Massachusetts study included three more years of follow-up and had a mean interval between the start of military service and death due to soft tissue sarcoma of over eleven years.

An Australian study of soft tissue sarcoma in Vietnam veterans from that country reported no excess. It is not clear, however, whether the soldiers or support personnel whose mortality experience was analysed were likely to have been exposed to Agent Orange.[16] Two other similar mortality studies were done in West

TABLE 3 *Case-specific information for connective tissue cancer deaths among Vietnam veterans by histological type and occupation*

Case	Age at death	Year inducted	Year discharged	Year of death	Histological type	Occupation on death certificate
1	30	1969	1971	1975	Fibrosarcoma	Data processing
2	28	1967	1970	1976	Synovial sarcoma	Manager
3	30	1965	1967	1976	Liposarcoma	Mental health assistant
4	32	1967	1972	1977	Fibrosarcoma	Manager
5	30	1964	1967	1977	Fibrosarcoma	Engineer's aide
6	32	1970	1971	1978	Fibrosarcoma	Civil engineer
7	32	1970	1971	1982	Epithelioid sarcoma	Graphics
8	29	1971	1974	1982	Sarcoma, nos	Firefighter
9	39	1961	1966	1983	Hemangiopericytoma	Picker (optical)

Virginia[17] and Wisconsin[18] using records that differentiated between veterans who received bonuses for service in Vietnam or were otherwise determined to have been in-country and those who were not. Their results were quite similar to those in the present study; in addition a comparison between Wisconsin Vietnam-era veterans and the general population showed increased mortality due to soft tissue sarcomas. A study of soft tissue sarcomas identified in Veterans Administration Patient Treatment Files[19] reported no association with military service in Vietnam. This study excluded 38% of cases originally identified from patient files and raises questions of selection bias in both cases and controls. In the Massachusetts mortality data, only two of nine soft tissue sarcoma decedents were reported to have been patients at VA hospitals.

The present study was not based on either adequate numbers of deaths or adequate exposure information to help resolve this important aetiological issue. Nevertheless, the highly significant excess of this rare malignancy in Vietnam veterans is important information. The latency period for soft-tissue sarcoma in adults is probably sufficiently long that several more years of observation will be necessary before any conclusive findings can be made.

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(Revised version received April 1987)

THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 30

The Honorable Alan Cranston
Chairman
Senate Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510-6375

Dear Mr. Chairman:

I am pleased to enclose replies to the questions you sent me in your letter of June 3, 1988 and the supplemental questions of June 6, 1988 all pertaining to the Agent Orange hearing on May 12, 1988 before the Senate Committee on Veterans Affairs. I am particularly anxious to reply, for the record, to those questions submitted by Senators Daschle and Kerry. Epidemiological terminology is not always clear to those who are not scientists and it would appear that there has been some confusion in their understanding of what is "significant" versus what is "statistically significant".

The response is necessarily long; to shorten too much would do injustice to the concerns of both Senators Daschle and Kerry. The Agent Orange issue is a complicated one that will get only more involved as more relevant publications appear. If all of the data were supporting one opinion, it would be an easier matter to make a decision. However, we are not so fortunate; but, that is the nature of science. We have accepted that role to make judgements on scientific issues and we attempt to weigh all of the data at hand ....not merely picking an isolated set of circumstances to make a specific point. This issue is a very important one to understand when attempting to weigh the importance of a particular study or subset of a larger study. To pull an isolated piece of data out of context, especially when that piece has no statistical significance, is not arguing within sound scientific principles. This type of isolation of "information" is the type of arguments that we are being faced with.

Should you have any further question, please do not hesitate to ask.

Sincerely,

Don Newman

Don M. Newman
Chairman, Domestic Policy Council,
Agent Orange Working Group

Enclosure

Follow-up Questions for May 12, 1988, Hearing on
Agent Orange Legislation and Oversight Issues
from Senator Alan Cranston, Chairman, to
the Agent Orange Working Group

Question #1	Please evaluate the written testimony (copy enclosed) submitted by Dr. Thomas Gasiewicz, who testified at the Committee's May 12 hearing on behalf of the Vietnam Veterans of America.
Answer	Dr. Gasiewicz's basic premise is that the results of studies on experimental animals should be taken into account in evaluating the potential health effects of dioxin in humans. There is little argument with this suggestion, and animal data have played an important role in pointing out the sorts of health effects that should be evaluated in studies of humans who have been potentially exposed to dioxin. It is not clear if Dr. Gasiewicz proposes that animal data be used beyond this scope and be relied upon to establish actual health effects in humans. If this is the case, there would be less agreement. The overall findings in different animal species are not as consistent as the few examples selected by Dr. Gasiewicz. In different animal species, the toxicity of dioxin, in terms of dose and toxic effects, varies a great deal. Therefore, the Review Committee of the American Academy of Clinical Toxicology concluded that extrapolation of findings in animals to humans would lead to tenuous predictions (Clinical Toxicology 1985-23:195).

The main reason Dr. Gasiewicz gives for the need to rely on animal data is that human studies have been flawed by lack of data on amount of exposure and inadequate measurement of sensitive indicators of toxic effects. The recent development of a highly sensitive serum dioxin assay and its use in comprehensive health studies of people exposed to dioxin overcome these limitations. The evaluation of a number of sensitive health measures relative to serum dioxin level in the ongoing Ranch Hand Morbidity Study and the National Institute for Occupational Safety and Health Study of phenoxy herbicide production workers should go a long way toward resolving the issue of human health effects of dioxin. Dr. Gasiewicz summarizes the animal data on toxic effects of dioxin on the immune system and applies his interpretation to humans as he states "Due to the lack of appropriate human data". While there is not as much data on humans as there is on animals, recent data on the immunological effects of dioxin in humans is available. This human data (the Air Force Health Study, Oct. 1987; the Centers for Disease Control (CDC) Vietnam Experience Study (VES) study, May 1988; the CDC study of Missouri residents) indicate that there are no long-term immune deficits in humans at exposure levels encountered by the populations studied. Dr. Gasiewicz's conclusions from extrapolation of animal data is not supported by these recent studies in humans using state-of-the-art immunological techniques, including cell counts, functional stimulation assays and test of delayed hypersensitivity.

Question #2 Senator John Kerry, in his written statement for the Committee's May 12 hearing (which he inserted in the Congressional Record on May 13 [copy enclosed]), described a number of Agent Orange-related studies. Please provide your assessment of his description of and conclusions drawn from each study, as well as his overall conclusions regarding the effects of Agent Orange. In your answer, please list each study and follow with your individual evaluation.

Answer Assessment of Senator John Kerry's overall conclusions regarding the effects of Agent Orange are based on data from about one dozen epidemiological studies. The studies cited by Mr. Kerry fall into three general categories:

(1) studies of U.S. Air Force personnel who were engaged in the serial spraying of herbicides in Vietnam (i.e., Ranch Hand Study); (2) studies involving groups of Vietnam veterans other than Ranch Hands; and (3) studies involving agricultural and forestry workers who handled herbicides as part of their employment.

The Ranch Hand studies are not relevant to the vast majority of Vietnam veterans since many Ranch Hand personnel had recognized heavy exposure to Agent Orange, while the average U.S. Army combat veteran in Vietnam does not appear to have been heavily exposed to Agent Orange based on the CDC Agent Orange Validation Study. The studies of non-Ranch Hand Vietnam veterans are of little relevance to the Agent Orange issue since there is no documentation of actual exposure to Agent Orange in these studies that would permit subdivision of the total study group into subgroups denoting a gradient in exposure.

Some of the cited studies of Vietnam veterans involve small numbers of cases of specific diseases that preclude drawing firm conclusions. Also, Mr. Kerry has reported almost any instance where the Vietnam study group experienced an increased incidence of some health outcome compared to other veterans, no matter how small and inconsequential the actual numbers were and whether or not the difference between the two groups was statistically significant. This highly selective use of study results does not support a conclusion one way or another on any issue. The studies of agricultural and forestry workers are not applicable to Vietnam veterans (at least non-Ranch Hand) because the former groups consisted of herbicide sprayers and handlers whose exposures would have been much higher than those of the average Vietnam veteran.

Senator Kerry appears to give equal weight to observations of studies whether they represent statistically significant findings or not. He also cites "reported" data with the same confidence as validated and confirmed data. In contrast to his inventory of adverse health findings in the VES, only alcoholism, psychological problems, abnormal sperm studies and hearing loss were validated by the physical examination portion of the study.

Question #3 Senator Tom Daschle, in a supplemental statement (copy enclosed) submitted following the May 12 hearing, discussed his concerns regarding what he termed "discrepancies" between certain testimony at the hearing and reports he had been given on the "status and details of several of the studies covered in the hearing." Please provide your assessment of his statements with respect to:

Question #3a The evidence linking dioxin with suppression of the immune system.

Answer Senator Daschle is correct in his claim that there is some evidence to suggest an effect of dioxin on the immune system. As noted in his testimony, however, the evidence is not direct, but is indirect. This indirect evidence comes primarily from studies of animals and shows that, in various species, dioxin suppresses or alters immune function. Extrapolation from animals to humans is difficult, because the extrapolation must account for dose, metabolism, and interspecies differences. Although immunosuppression has not been conclusively documented in humans, it is reasonable to speculate from animal studies that at least at high exposure levels the human immune system could be affected by dioxin. Unfortunately, it is not known what level of exposure would be necessary to affect human health adversely.

The evidence from human studies seems to indicate that there is no long-term adverse effect of dioxin on the immune system. The Ranch Hand study found no consistent effect, even after considering the statistical interactions of smoking, race, occupation and alcohol use. There was no discernible pattern suggesting any detriment to any subgroup of the Ranch Hands, and the authors concluded that there was no effect. The Advisory Committee agreed with this conclusion.

Question #3b	Mr. Newman's comments on the relationship between Agent Orange and adverse health effects as epitomizing the "Administration's tendency to over-simplify, downplay, or blatantly misrepresent scientific evidence suggestive" of such a relationship.
Answer	As stated in in my earlier testimony, this Administration has focused attention at the highest levels on the Agent Orange issue resulting in over $90 million in research expenditure.
Question #3c	The testimony by the Air Force witnesses and the merits of the Air Force Ranch Hand Study.
Answer	The Agent Orange Working Group has complete confidence in the U.S. Air Force Ranch Hand Study and in the monitoring function and peer review by the Advisory Committee. I have no further comments to make with regard to other allegations. My response to the Committee concerning the Air Force witness, Dr. Albanese, is contained in my letter and analysis of June 9, 1988 (copy attached).
Question #3d	The National Cancer Institute's Study of Kansas farmers and the relevance of the study results to Vietnam veterans' exposure to Agent Orange. Please also comment specifically on each of the possible conclusions which Senator Daschle states can be drawn from that study.

Answer The NCI study may be of some relevance to the subgroup of Vietnam veterans who actually sprayed herbicides, but it does not appear relevant to the average Vietnam veteran who most likely did not have heavy exposure to Agent Orange based on the results of the CDC Agent Orange Validation study.

In reference to Senator Daschle's "possible conclusions";

1. The increase in NHL is unrelated to the 2,4-D/dioxin mixture.

   Comment: This is the least likely conclusion.

2. 2,4-D is the cause of the increase.

   Comment: This is a likely possibility, especially if any non-dioxin contaminants of 2,4-D are included as possible causes.

3. 2,4-D and dioxin worked together to cause the increase.

   Comment: This possibility seems to suggest an interactive effect of two substances. Such a mechanism of action is difficult to assess in this situation.

4. Dioxin is the cause of the increase.

   Comment: This is a possibility although it would mean that dioxin isomers of less toxicity than 2,3,7,8 TCDD are carcinogenic.

Question #3e The VA's Proportionate Mortality Study.

Answer The Agent Orange Working Group gave the Senate Committee its views on the VA's Proportionate Mortality Study in my letter to you and the Committee dated October 9, 1987 (copy attached).

Question 3f The importance of adjusted analyses, particularly with respect to the Ranch Hand Study.

Answer When interaction occurs, stratified analyses must be conducted, and patterns and consistency within these additional analyses must be assessed. The interaction may or may not demonstrate consistency and may or may not be biologically plausible. After careful analysis, the authors of the Air Force report concluded that there was no consistency in the data and no discernible patterns indicating adverse effect of dioxin on the immune system. The "adjusted analyses" of the Ranch Hand Study is basically an expansion of the discussion section of the 1984 Ranch Hand Base-line Morbidity Report. This analysis focuses on 11 selected areas of morbidity and on the fact that the herbicide exposure index used in that report was probably quite imprecise. The five "significant" morbidity measures described as being in excess among the Ranch Hand group, are either undergoing validation or are not supported by subsequent work. The exposure index issue is also being resolved since the Air Force will obtain serum TCDD levels for use as their criterion of exposure. In summary, this reanalysis does not suggest any new interventions or new directions for the United States Air Force Health Study.

Question 3g The Centers for Disease Control's (CDC) Vietnam Experience Study, particularly regarding the findings about birth defects.

Answer Senator Daschle's general comments concerned the presentation of results and scrutinizing the positive findings until these findings could be explained away. We believe the Journal of American Medical Association (JAMA) articles represent a balanced presentation of the findings from this study. Our results were peer reviewed on a regular basis and the JAMA articles were reviewed by the Office of Technology Assessment and the JAMA reviewers prior to publication.

With respect to the issue of non-Hodgkin's lymphoma, we have explained that the Vietnam Experience Study was not designed to evaluate the risk for specific types of cancers. This was originally addressed in the study protocol (1983) and is the reason the Selected Cancers Study is being conducted. The CDC is concerned about the non-Hodgkin's lymphoma findings to date and believes close attention should be given to the ongoing studies (e.g., Selected Cancers Study) which will provide additional data in this area.

Senator Daschle also expressed concern about the birth defects data from the Vietnam Experience Study (VES). He states that, for the hospital birth records substudy, "only a small, nonrandom subsample of the birth records were checked," and that there are problems with this approach. He states it would be preferable to (1) verify all birth defects or at least a larger random subsample, and (2) verify birth defects using medical records or examinations instead of hospital birth records.

We believe that Senator Daschle's comment about the size and representativeness of our subsample is misleading. We examined the birth records of over 3,000 children. This substudy was large enough to detect a relative risk of 1.4 for total birth defects. Our findings showed no difference at all between the two cohorts; the relative risk was 1.0. We have no reason to believe that these findings would have been different if the subsample had been larger or that they are, in any way, the result of the size of the sample.

With regard to the representativeness of the subsample, the children included are the children of approximately half of the veterans who completed the physical examination. Detailed analyses of the examination participants relative to the telephone interview participants showed these groups to be very similar. In addition, participation in the birth records substudy was very high in both cohorts, and, moreover, the two cohorts were similar with respect to various demographic and military characteristics. Thus, there is no evidence of selection bias or participation bias in this substudy. We believe that the children in this substudy are representative of all children reported in the interview.

In collecting medical records, we limited the time period to the immediate postbirth interval, as opposed to a longer time period, for three reasons. First, the main purpose of studying these records was to use an independent source of data to verify or refute the cohort differences found in the interview data.

Our interest was not so much in the absolute validity of the rates of total birth defects, but in the relative validity of the cohort comparison. While those birth defects evident at birth do not represent all birth defects, we had no reason to believe that the comparison of this subset of birth defects between the two cohorts would not be valid. Second, this approach was less subject to potential reporting bias because it relied only on the accurate reporting of time and place of birth. If we had collected medical records for a longer postbirth time period, we would have had to rely on veterans' reports of hospitalizations, clinic and physicians visits, and dates, places, and provider names for these services. If the two cohorts differed in their ability or willingness to accurately report such information, the ultimate collection of medical records would be biased. Lastly, it was feasible to collect and analyze birth records for a subgroup of children within the time frame of the other VES study components so that all results could be interpreted and presented simultaneously.

Question 3h The CDC's cancelled Agent Orange Study, particularly regarding conclusions drawn from that study about the lack of substantial Agent Orange exposure among ground troops in Vietnam.

Answer There are several important points to consider in evaluating the results of the TCDD Validation Study in drawing conclusions about Agent Orange exposure among ground troops in Vietnam. First, the study design of the Validation Study permitted the evaluation of five different military records-based exposure scores, as well as self-reported exposure by the veteran. The "hits" model was not the only method evaluated in this study. There was no association between TCDD levels and any of the five records-based exposure scores or self-reported exposure.

Second, the median TCDD level in the Vietnam veterans and non-Vietnam veterans was identical-3.8 parts per trillion (ppt). About 1% (9 veterans) of the Vietnam sample and 3% (3 veterans) of the non-Vietnam veteran sample had current TCDD levels greater than 10 ppt. Two Vietnam veterans and no non-Vietnam veterans had levels above 20 ppt--one with 25 ppt and another with 45 ppt. The veteran with 45 ppt reported no exposure (military or cilivian) and the veteran with 25 ppt reported 180 days of indirect military exposure (defined as walking through or clearing vegetation in a previously sprayed area), plus 1 day of home use of herbicides. Both men reported their health is excellent, with no health problems perceived as a consequence of exposure to Agent Orange.

Third, the 646 Vietnam veterans served an average of 320 days in tactical battalions which operated in the heaviest sprayed area of Vietnam (III Corps) during peak years of Agent Orange spraying (1966-69).

And fourth, at the same time the Validation Study was being carried out, CDC was measuring TCDD levels on a group of Air Force health study participants in the U.S. Air Force and CDC study of the half-life of TCDD. Of the 147 Ranch Handers whose TCDD values were measured, 25 had current TCDD levels between 50-100 ppt, 16 between 100-200 ppt, and 5 over 200 ppt. All but 1 of the 49 veterans in the comparison group had TCDD levels less than 10 ppt.

These data, as well as data from the National Institute for Occupational Safety and Health Pilot Study of Herbicide Production Workers and the New Jersey Pointman Project, show that substantial TCDD levels can be detected in occupationally exposed individuals whose last known exposure occurred 15 to 20 or more years ago. The data also suggest that the average ground troop probably did not have unusually heavy dioxin exposure in Vietnam.

Question 3i	Government interference in dioxin studies, especially in peer review procedures, and the effects thereof.
Answer	I am deeply distressed at Senator Daschle's statements concerning the peer review and monitoring standards in Government Agent Orange and Dioxin Studies and his allegation of "Government Interference by OMB and the White House Agent Orange Working Group". I am aware of not one single instance of OMB, which is a key member of the Agent Orange Working Group, ever interfering in any such studies. Despite the Administration's attempt at fiscal restraint and a policy of responsible spending, this has never been applied to these studies. The reverse happens to be the fact. The record will show that years of effort and millions

of dollars have been allocated to these studies because of the Administration's high priority placed on this issue and the President's promise to the Vietnam Veteran.

With regard to peer review, The Advisory Committee to Study the Long Term Health Effects of Phenoxy Herbicides and Contaminants, was established specifically at the request of the White House in 1979 and is chaired by a highly respected researcher at the National Cancer Institute, Dr. Robert Miller. He is not a White House appointee. The Charter establishes that the Committee shall be composed of eminent scientists from the academic world. Furthermore, at the time of the Committee's formation we called every major veterans organization to request recommendation for and concurrence on the membership. This was obtained. As I wish to assure the Committee of the complete independence of the Advisory Committee, I suggest that Senator Daschle address any specific remarks directly to Dr. Robert Miller.

Senator Daschle expresses his concern that there has been undue government and management interference with the conduct of dioxin research. The Air Force investigators have been clear in their statements to Senator Daschle and in their testimony on 12 May that there has not been any interference in their work. They have been free of interference throughout the study and all conclusions have been reached on the basis of scientific merit. The Advisory Committee of the Agent Orange Working Group provides review and oversight functions and their advice and council has been extremely valuable to the study. At no time has there been technical direction of the study from nonscientific elements of the government. The Air Force management structure limits its impact on the study to purely administrative matters of funding, manpower and equipment management. A statement was made in the Protocol of the Air Force Health Study (AFHS) (written in 1978 and 1979) that a committee should be established to provide scientific review of the study and guidance to the Air Force investigators. The Advisory Committee has periodically recommended modification to preliminary versions of AFHS documents and reports. Changes made to the documents and reports were made to address scientific issues raised during the review process and were made only for valid scientific reasons. The suggested makeup of that committee included a "veteran's representative". The Protocol statements were written prior to the establishment of the Science Panel of the AOWG, and were intended by the authors of the Protocol as a guide to the creation of an external review group. These statements were never intended to be part of the scientific portion of the Protocol, but were administrative in nature. These suggestions were superseded by the creation of the Advisory Committee by the AOWG. The current Air Force investigators are firmly committed to the position that membership on the Advisory Committed should be based primarily on scienfitic accomplishment and expertise.

[Enclosure Question 3c]

THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN - 9 1988

The Honorable Alan Cranston
Chairman
Senate Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510-6375

Dear Mr. ~~Chairman~~ Mr Chairman:

As I promised in my letter to you of April 21, 1988 enclosed is the review you requested of the Interim Report by Dr. Richard A. Albanese entitled "United States Air Force Personnel and Exposure to Herbicide Orange" (USAFSAM-TR-88-3).

I requested the Science Panel of the Domestic Policy Council Agent Orange Working Group (DPC/AOWG) to conduct an indepth review of the study and I am appending both the summary report from Dr. Ronald Hart, who chairs the Science Panel and the individual comments of key members of the panel. There is unanimity of opinion as to the merits of this report and the findings which warrant follow up investigation or analysis are identified.

Please do not hesitate to contact me should you have further questions.

Sincerely,

Don Newman

Don M. Newman
Chairman,
Domestic Policy Council
Agent Orange Working Group

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Phone (501) 541-4000
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National Center
For Toxicological Research
Jefferson AR 72079

MAY 23 1988

The Honorable Donald M. Newman
Chairman, Domestic Policy Council
Agent Orange Working Group
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 614-G, HHH Building
Washington, D. C. 20201

Dear ~~Mr. Newman~~ Don:

In response to the Congressional request, the AOWG Science Panel members were asked to review the Interim Report by Dr. Richard A. Albanese entitled "United States Air Force Personnel and Exposure to Herbicide Orange" (USAFSAM-TR-88-3). I would like to submit to you the enclosed summary along with the individual reviews in response to this request.

I wish to thank the following individuals for taking time to review this report and submit written comments: Dr. Vernon N. Houk, CEHIC/CDC; Dr. Marilyn A. Fingerhut, NIOSH/CDC; Dr. Lawrence B. Hobson, VA; Drs. Terry L. Thomas and Han K. Kang, VA; Dr. Carl A. Keller, NIEHS; and Dr. John F. Young, NCTR. Reviews from the Air Force members of the AOWG Science Panel are obviously missing; this is by design due to the controversy surrounding this article. Ms. Hellen Gelband's OTA review was not included with this summary by choice since it was sent directly to Congress in response to their own Congressional request; however, there are no inconsistencies between the reviews. A copy of the OTA review is included for your perusal, but not for inclusion with the rest of the AOWG Science Panel reviews.

At the AOWG Science Panel meeting scheduled for June 1, 1988, this report will be open for discussion.

If more information is needed, please do not hesitate to ask.

Sincerely,

Ronald W. Hart, Ph.D.
Chairman, AOWG Science Panel
Director, NCTR

Enclosures

Summary of AOWG Science Panel Reviews of "United States Air Force Personnel and Exposure to Herbicide Orange" by Richard A. Albanese, February, 1988. (USAFSAM-TR-88-3)

Reviews were submitted by Dr. Vernon N. Houk, CEHIC/CDC; Dr. Marilyn A. Fingerhut, NIOSH/CDC; Dr. Lawrence B. Hobson, VA; Drs. Terry L. Thomas and Han K. Kang, VA: Dr. Carl A. Keller, NIEHS; and Dr. John F. Young, NCTR. [The individual reviews are attached as part of this summary.]

This report is a reassessment of the Baseline Morbidity Study Results from the 1984 AFHS of Ranch Hand veterans. Several of the reviewers questioned why the data were being reassessed at this time, why this reassessment did not take into account the literature references since 1984, and especially why the October, 1987 AFHS, First Followup Examination Results report was ignored? It would appear that Dr. Albanese has only slightly modified the original 1984 document to make a case to implicate Agent Orange in some findings of rather questionable significance. Of the five "significant" clinical areas mentioned by Dr. Albanese as being in excess among the Ranch Hand group, one is still undergoing validation (patent-reported birth defects) and the other four are not supported by the October, 1987 AFHS followup report.

There was general criticism of this technical report in respect to its lack of detail on study methodology, statistical procedures, and definitions of terminology. There was also a lack of consistency in the statistical analysis and data presentation from one table to the next. (Table 12, p. 21, is clear and contains sufficient information; however, it is the only one with this format.)

There is general agreement that the results from this study can neither implicate nor exonerate Agent Orange as the causative agent. However, with the current (1988) state of knowledge and ability to quantitate the TCDD serum levels of these individuals, this continuing research effort of the AFHS has the potential to provide very useful information regarding health effects in Agent Orange "exposed" individuals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date April 18, 1988

From Director, Center for Environmental Health and Injury Control

Subject Review of USAF Technical Report

To Ron Hart, Ph.D.
Chairman
Agent Orange Working Group Science Panel

This paper appears to be intended as an expansion of the discussion section of the 1984 Ranch Hand "baseline" morbidity report. It focuses on 11 selected areas of morbidity and on the fact that the herbicide exposure index used in that report was probably quite imprecise.

The Ranch Hand study staff now readily concede that their original herbicide exposure index was of unknown validity, and they are now working with the CDC Environmental Health Laboratory Division in obtaining serum TCDD levels for use as their criterion of exposure. Part of Albanese's critique has, therefore, become moot.

The 11 areas of morbidity selected for discussion were chosen by Albanese because of biological plausibility (a review of the literature relating to each of these areas). Five of these 11 areas were identified by Albanese as having definite statistical differences between the Ranch Hand and the comparison group, with more pathology being shown in the Ranch Hand group in every one of the 5. His main point is that the consistent direction of the differences is an important feature.

Let us look at each of these five areas with higher prevalence of abnormality among the Ranch Hand group:

1. Neoplasia - There appears to be a medical-record validated small excess of skin cancers among the Ranch Handers, all of whom served for extended periods in South Vietnam. We are not told anything about the amount of duty time in the tropics among the comparison group, nor of postwar residence in southerly latitudes in either group. The 1987 Ranch Hand follow-up results, when adjusted for lifetime latitude of residence, show no difference in skin cancers.

2. Birth defects - There is an excess of birth defects reported by Ranch Hand parents, and Albanese notes that "intensive work is in progress [seeking medical confirmation of the defects], addressing both differential over- and underreporting." The Ranch Hand 1987 follow-up does not cover this activity, and the VES has found evidence of greater underreporting by non-Vietnam fathers, thus

creating the "excess" of reported birth defects in the Vietnam group. When birth records were retrieved and used as the basis for "blind" computation of rates, the group differences disappeared.

3. Psychological - No psychological group differences were found in the 1987 Ranch Hand follow-up. The VES has found a pattern of excess anxiety, depression, and alcohol abuse or dependency in the Vietnam group, along with evidence of other stress-related symptoms. This is not surprising, given the nature of the Vietnam experience for ground troops.

4. Hepatoxicity - The listing of liver-related variables (Table 10) provides no evidence of significant group differences, and in 7 of the 9 tests shown the comparison group has a higher percentage of men outside the normal ranges. It is hard to see how Albanese makes a case out of this. Perhaps it was the subgroup analyses, showing excesses of SGOT and LDH abnormal values in some self-reported alcohol strata. The 1987 Ranch Hand follow-up shows no covariate-adjusted differences between the two groups except for:

   a. more SGPT abnormalities in the comparison group and
   b. more alkaline phosphatase abnormalities in Ranch Handers.

   The VES found only G-glutamyl transferase elevations in the Vietnam group (5.5% versus 4.4%), of marginal significance (OR=1.3; 95% CI 1.0-1.8).

4. Cardiovascular - The excess of clinically-defined peripheral pulse abnormalities (no Doppler test reported) mentioned by Albanese is not confirmed in the 1987 Ranch Hand follow-up report, where Doppler tests were included, and the VES, using Doppler testing, also found no group differences.

In summary, the five "significant" morbidity measures mentioned by Albanese as being in excess among the Ranch Hand group are either undergoing validation (parent-reported birth defects) or are not supported by subsequent work. It is interesting that the Air Force (in its flight and support personnel) is not finding the intergroup psychological differences found among ground troops.

Vernon N. Houk, M.D.

cc: John Young

Comments on the USAF Technical Report, "United States Air Force Personnel and Exposure to Herbicide Orange," February, 1988

Marilyn A. Fingerhut
April 22, 1988

This document raises many questions. Why was it written in 1988, reviewing data published in a 1984 report? Standard scientific procedure requires that the researchers interpret their results in light of reports in the literature. This 1988 document seems to provide the final chapter of that report, but four years after it should have been written. I do have a vague recollection that the USAF researchers were directed to release that original report on a particular date, regardless of the completion of the work. Is that recollection correct? If so, there are undoubtedly some lessons to be learned about releasing research only when the work is finished.

I found it difficult to evaluate the content of the 1988 report. Not enough detail was presented to permit the reader to follow the reasoning of the authors. In some sections, selected sections of the original report were repeated verbatim. In other sections, different numbers were reported. For example, Table 4 in the current report cites 13 Ranch Hand and 8 comparison systemic cancers, but Table X-1 (page X-3) of the 1984 report has 14 verified Ranch Hand and 10 verified comparison cancers.

The two sections singled out by the congressmen for comment were neoplasia and reproductive effects. The 1988 report seems to indicate that it was erroneous to report that in 1984 that excess cancers were confined to the skin, because the a priori hypothesis required testing skin and systemic cancers together. Since the 1988 report presents only a summary of the information, it is not possible for a reader to evaluate the data used by the authors. However, the risk ratios do not seem to be very different from the original 1984 report. The effect reported for the cardiovascular system seems to be based on the peripheral pulse results; however, it is unclear whether the researchers adequately accounted for smoking in the Ranch Handers.

The 1988 report also increases the confusion about reproductive effects. The document is still based upon self-reported outcomes, raising the question of why the authors didn't wait until the verified medical record analysis was completed. Additionally, it is difficult to determine by reading the 1988 report how thoroughly the analyses were conducted.

In my opinion, the release of this document adds confusion to the issue of accurate assessment of exposure of the Ranch Handers to Agent Orange, and to the interpretation of the results of the study. We are well aware that the blood levels of 2,3,7,8-TCDD being collected in the current medical examination provide a valuable mechanism to estimate exposure to Agent Orange. That reality is ignored in the document, which acknowledges the necessity of an improvement in the exposure matrix used in that 1984 report. The description of the exposure index on page 3 of the 1988 report fails to describe adequately how the exposure matrix used for the 1988 document differs from the one used in the 1984 report. Additionally the 1988 document fails to use or address the improvement in the exposure matrix promised in the 1984 report on page XVIII-2.

Why was this document written? Why was it released? It would have been helpful if the reasons as well as the limitations of the document had been more clearly expressed by the authors. How are we to interpret the content of this 1988 document with respect to the content of the results of the USAF report of the first five year followup report, "Air Force Health Study," published in October, 1987?

Because of the confusion generated by this report, it may be useful for the USAF researchers to take stock of the situation and develop a plan to produce a comprehensive report which integrates the results of the two completed studies and the current effort, and which utilizes a solid exposure matrix. We know that at least some of the Ranch Handers have high current body burdens of 2,3,7,8-TCDD; therefore, the research efforts have the potential to provide very useful information regarding health effects in Agent Orange exposed individuals. However, continued use of any exposure matrix which misclassifies individuals will delay the obtaining of valid results and will continue to confuse readers and increase skepticism about the scientific quality of the research.

It is my understanding that the researchers are considering publication of results in the scientific literature. This is a delayed, but commendable goal. It would be most useful if the publication(s) presented a comprehensive and current assessment of the health of the Ranch Handers and the comparison group, using a solid exposure matrix to evaluate dose-response effects. The researchers may want to consider waiting until the current medical exam is completed, so that all prior results can be reevaluated and integrated using a solid exposure matrix based upon blood levels of 2,3,7,8-TCDD. The alternative seems to be a continuation of issuing outdated information, such as appears in the 1988 report we are reviewing.

COMMENTS ON "UNITED STATES AIR FORCE PERSONNEL AND EXPOSURE TO AGENT ORANGE,"
RICHARD A. ALBANESE, M.D., USAFSAM-TR-88-3,
FEBRUARY 1988

1. The Albanese report examines 11 clinical variables among the 13 or more considered in the Baseline Morbidity Study Results published by the USAFSAM in February 1984. In selecting the 11 variables, Albanese used prior animal and human results as reported in "more than 400 dioxin-related published articles" (p. 1) of which 58 are listed in the bibliography. The review of animal data is interesting and valuable in demonstrating the variation of results among various species and especially in emphasizing the lack of correlation between dioxin's effects on lower animals and those on man.

Note "p.1" refers to pages in the Albanese review, "P." to pages in the "First Follow-up Examination Results" and "p=" to probability

2. The data cited by Albanese are all reported in the 1984 study and all the tables are either reprinted or derived directly from those in the earlier report with the exception of Table 19, "Summary of Findings." The result is a condensation and selection of data to support Albanese's conclusions that, "at this time one cannot ascribe the observed group differences (between Ranch Hands and unexposed controls) to an effect of dioxin." "However, the AFHS (Air Force Health Study) does not exenerate dioxin as a causative agent of these group differences." "Further clarification of the role of dioxin in human health must await the results of the follow-up phases of the AFHS and other ongoing epidemiological studies of dioxin-exposed groups." (p.29)

3. The conclusions are not inconsistent with those of the 1984 report which ends, "The report concludes that there is insufficient evidence to support a cause and effect relationship between herbicide exposure and adverse health effects in the Ranch Hand group at this time." Of interest, therefore, is whether Albanese's analysis might be modified by the results of a re-examinaion of the Ranch Hand and control groups some three years after the first examination. These results are contained in the "Summary" of the "First Followup Examination Results," issued in October 1987. The voluminous detailed results in some 1,000 pages are available but not generally circulated.

4. Albanese's analysis included body fat calculation as an index of general health; there was no statistically significant difference between Ranch Hands and controls. (p. 9). On re-examination, the Ranch Hands were leaner than the controls (p=0.037) but had a significantly (p=0.002) higher sedimentation rates (P.4). A "nonspecific assessment of general physical health," however, showed close similarity of the two groups (P.4).

5. Albanese emphasized the greater prevelance of skin cancer (p=less than 0.01) among Ranch Hands (p.10) at the first examination. A marginally significant higher rate (p between 0.05 and 0.10) persisted among Ranch Hands with a significant higher life-time incidence (p=0.035) for basal cell carcinomas (P.8). There was, however, no difference between Ranch Hands and controls in the incidence of such carcinomas during the interval after the initial examination. (P.9).

6. In considering possible reproductive effects, Albanese noted that increased birth defects among children of Ranch Hands ($p=0.04$) represented the only significant difference (p.14-15). The 1987 report contained no new data regarding birth defects because the Air Force is conducting an exhaustive search for the medical records of all offspring of Ranch Hands and controls.

7. Albanese considered that there were no significant differences in neurological findings between the two groups. (p.16). No discrepancies appear on the re-examination. (P.9-13).

8. Extensive psychological testing during the first examination led to significantly greater evidence of fatigue, anger, mental erosion, anxiety, isolation and depression among Ranch Hands than among controls as pointed out by Albanese (p.17). These differences were diminshed in many areas on the second examination; denial and abnormal masculity/feminity on the MMPI were greater among the controls. As in the earlier tests, educational level, age and alcohol use were dominant factors in test performance (P.14-16).

9. Albanese gave considerable attention to the nine laboratory tests used to evaluate liver function (p.18-19). The results, unadjusted and adjusted for a variety of factors known to influence hepatic function, were equivalent for Ranch Hands and controls. Albanese, however, calculated SGOT-alcohol regression slopes and found that for Ranch Hands significantly steeper than that for controls. Similar results for LDH-alcohol and LDH-degreasing chemicals regression slopes had p values of 0.011 and 0.037 respectively. No regression slopes are given for the other liver function tests (SGPT, GGPT, alkoline phosphatase, total bilirubin, direct bilirubin, cholesterol and triglycerides) nor for the other covariants (non-herbicide industrial chemicals and antibodies to hepatitis B surface antigens). The suggestion that exposure to Agent Orange increases adverse effects of subsequent exposure to covariant noxious agents is greatly weakened if it occurs in only 3 of the 36 possible combinations of Agent Orange and other exposures. No statistically significant differences were found among the three measures of porphyrin metobolism; the coproporphyrin-alcohol regression slope was just significantly steeper ($p=0.045$) among Ranch Hands (p.20). On re-examination, Ranch Hands had significantly higher alkaline phosphatose values ($p=0.008$) and coproporphrins but controls had greater SGPT values ($p=0.048$) and uroporphrins ($p=0.048$) (P.18-19). The liver size on physical examination was more often increased in Ranch Hands as it was on the first examination.

10. Albanese detected no significant differences between the two groups as regards skin lesions. (p.20-21). The later examination revealed only an increase incidence of acne after service in South East Asia among Ranch Hands and this was of borderline significance (P.20-21). No chlorance has been found on any examination.

11. Albanese noted that peripheral pulses were reduced significantly more often ($p=0.05$) among Ranch Hands but that heart disease was no more frequent than among controls (p.21-22). On re-examination and with pre-test smoking prohibited, the difference in peripheral pulse patency disappeared (P.25). Of 27 cardiovascular variables evaluated only "Verified heart disease" was more common among Ranch Hands ($p=0.054$ unadjusted and 0.036 adjusted), a finding not supported by other information (P.22).

12. No statistically significant differences between Ranch Hands and controls were found by Albanese among the tests used to detect reduced immunological response at the first examination (p.22-24). More tests were included in the second examination but again failed to detect differences (P.35).

13. Albanese pointed out that Ranch Hands had a significantly increased ($p=0.02$) tendency for a high T_3 uptake and a greater decrease with age ($p=0.026$). Two-hour post-prandial glucose levels also increased more rapidly with age in Ranch Hands ($p=0.006$). Ranch Hands had a somewhat higher testosterane levels (p.25-27). Reexamination failed to detect significant endocrinological differences between the two groups, variations being attributable to such factors as age, race, and percent body fat (P.31-33).

14. It thus seems that of the factors Albanese selected as of significance only two have retained significantly different values after the second examination of the groups: basal cell carcinoma of the skin and verified heart disease, the latter only marginally different and never ascribed to Agent Orange. The data on birth defects are not yet available; those from psychological testing remain contradictory. Liver functional defects have not been clearly demonstrated as of greater frequency in Ranch Hands and the results of tests are confusing.

15. Of special interest is the failure to detect porphyria cutanea tarda, soft tissue sarcoma, lymphoma, lung cancer, or chloracne as consequences of Agent Orange exposure. All have been said to be caused by the herbicide.

4/17/88

LAWRENCE B. HOBSON, M.D., Ph.D.,
Director, Agent Orange Projects Office

USAF Technical Report
"United States Air Force Personnel and exposure to Herbicide Orange"

The quality of this study is difficult to evaluate because the technical report does not provide sufficient detail on study methodology, statistical procedures, or definitions of terminology. A great deal of information was collected on each study subject and it appears as if some appropriate statistical analyses might have been performed; however, the descriptions of how data elements were collected and of the various statistical techniques are inadequate. Furthermore, while this report is described as "Interim Report for period March 1986-February 1988" no data from the second morbidity report released in October, 1987 by the Air Force is included or considered in this report. This report could be strengthened by adding the first follow-up examination results.

In the description of the methodology, no detail is provided regarding the questionaire items or how interviews were conducted. No information is provided regarding whether the next-of-kin interviews obtained for deceased subjects were actually used in the analyses of morbidity data. It was not clear whether the next-of-kin interviews for living subjects were used to supplement information provided by the subjects themselves, or how they might have been used if contradictory information was provided. In the presentation of results, it is not clear for some of the various outcome measures whether information was taken from the physical examination reports, from the interview data, or a combination of both.

On page 7, paragraph 1, the total number of study participants is given as 2,269. In the next paragraph, the number of subjects included in the morbidity analyses is given as 1,818. It is not clear from the description provided in the text how the first number was derived.

A variety of statistical techniques were used to evaluate the outcome variables. The tables contain numbers of study subjects, percentages and p-values; however, the actual statistical techniques used change from table to table. No point estimates of relative risk or explanations of how they were derived are provided. Point estimates appeared to have been calculated using simple unadjusted rate ratios for some of the analyses and using logistic models for other analyses. For many of the tables, it was not possible to determine what technique was used to obtain a point estimate or from what hypothesis test a p-value was derived. The data would be much easier to interpret if the results had been presented as follows: number of ranch hand subjects who had the outcome variable, number of comparison subjects who had the outcome variable, relative risk point estimate, statistical methodology used to derive the point estimate, and a confidence interval around the point estimate or a p-value indicating whether it was significantly different from 1.0. Reference is made to analyses by Agent Orange exposure levels, but no results are shown.

The literature review for animal and epidemiologic studies cites articles published through 1984. Additional studies have been published since that time which provide further insight regarding health associated with herbicide exposure. These studies should have been added to the review.

A distinction is made between skin cancer and "systemic cancer" in the report. It is not clear whether the term "systemic cancer" refers to cancer of all other sites or whether it might refer only to lymphatic and hematopoietic cancers which could be considered to be "systemic". If the category "systemic cancer" indeed refers to cancers of all sites except the skin, the term is misleading, as there are many types of cancer that arise from other primary sites and in no way could be considered "systemic". It is not clear whether the term "skin cancer" refers to only non-melanoma skin cancer, or all skin cancer including melanoma. In addition, the term "neoplasia" is used interchangeably with "cancer", the former being a much broader term.

On page 11, last paragraph, mechanisms that could lead to unfavorable reproductive outcomes are discussed. Item "d", "transmission to the spouse by contact with clothes or other objects" seems highly unlikely for Ranch Hands. The variables listed under "Live Birth Outcomes" are not defined, and the source of the information is not identified. It is not clear whether only interview data was used to identify birth defects or whether the reports were verified by medical records. Since it appears that no medical records were used, the issue of response bias should be addressed. One of the few statistically significant results from the study was seen in this poorly-defined category. The definitions of the catergories of "severe", "moderate", and "limited" for birth defects are quite subjective. A better classification might have been by type of defect (i.e., specific medical diagnosis).

In the analyses of mortality data, no information is provided by cause of death. A statement is made regarding "complex patterns with date of birth and date of death" without further explanation or information.

Table 19 in the summary is misleading and is not accompanied by the appropriate caveats. Following are some of the specific problems:

(a) Weight loss is one of the effects reported in the literature to be associated with exposure to dioxin; however, this is an effect which has been measured shortly after exposure occurred. In the AFHS study the surrogate measure was percent body fat which was estimated many years after exposure occurred; thus, temporary weight loss associated with heavy exposure could not be measured.

(b) The increased risk of "neoplasia" in the AFHS study was confined only to "skin cancer" which was not further described in terms of cell type.

(c) The birth defects reported in the AFHS are not defined, nor is any evidence of medical confirmation provided.

(d) The increased risk of psychological changes in Ranch Hands is based on self-reported incidence of psychosis, alcohol dependence, or other neurosis. The difference was not statistically significant but is not distinguished in Table 19 from those results that are statistically significant.

(e) The positive result for hepatotoxicity reported in Table 19 is based on a non-significant slightly increased incidence of hepatomegaly among Ranch Hands on physical examination and a statistically significant difference for "medical history" of liver disorders other than hepatitis, jaundice or cirrhosis. There were no differences reported between the Ranch Handers and the comparison group for a series of 12 laboratory tests related to liver function.

(f) A positive observation for cardiovascular changes among Ranch Hands is reported in Table 19. However, no significant differences between the Ranch Hands and the comparison group are observed with respect to blood pressures, abnormal electrocardiogram, abnormal funduscopic findings. A marginal difference was observed in pulse rate, but the author reported that "the participants were allowed to smoke prior to the examination of the pulses, and more Ranch Hands smoked at the time of the examination than did comparison."

(g) The endocrine changes reported in table 19 are based only on one statistically significant result for one laboratory test.

(h) As mentioned earlier, no information is provided to determine whether there might be an elevated risk of mortality for any specific causes of death.

In summary, this report is relatively uninformative regarding the effects of exposure to herbicide orange among the Air Force Ranch Hands. Further detail regarding statistical analyses performed, point estimates for relative risk, and definitions of terminology should be provided. Table 19 is misleading and should be revised.

Prepared by:

TERRY L. THOMAS, Ph.D.
HAN K. KANG, Dr. P.H.
VA Office of Environmental Epidemiology

A Review of:

United States Air Force Personnel and Exposure to Herbicide Orange

Richard A. Albanese, M.D.
February 1988

Interim Report for Period
March 1984 - February 1988

Reviewed by:
Carl A. Keller, Epidemiologist
Division of Biometry and Risk
Assessment, NIEHS
April 28, 1988

The United States Air Force Personnel and Exposure to Herbicide Orange Interim Report is a reassessment of the Baseline Morbidity Study Results from the 1984 AFHS of Ranch Hand Veterans. It seems appropriate to review this interim report in the context of the original Baseline Study Results since the original report contains more analyses and more data, and, it is easier to determine how some conclusions were arrived at in the original report.

The abstract states that of the "Eleven clinical areas...based on a toxicological profile developed from the literature and availability of data in the AFHS...six [showed] statistically significant group differences....[including] five....in the direction of expected dioxin effects." A discussion of each of the 11 clinical areas are as folows:

1. Percent Body Fat - No difference was found between Ranch Hands and comparisons although laboratory data suggest loss of body fat as one of the symptoms of dioxin poisoning. Since data from laboratory animals indicates that loss of body fat is one of the manifestations of acute and continuing long-term dioxin intoxication, it is unlikely that it would be evident more than 10 years after exposure ceased.

2. Neoplasms - The report points out that there was a significant increase in total malignant tumors among Ranch Hands compared to the original controls, and suggests that this was the a priori hypothesis which was being tested and should have been reported as a strong positive finding. While this interpretation is in accord with the theory of statistical inference, any a priori hypothesis of an increase in unspecified malignancy was itself unsound. There were no cases among Ranch Hands of any of the tumors for which there was a reasonable basis for expecting an increase possibly caused by exposures to phenoxy herbicides and contaminants.

3. Reproduction - The report includes some new and preliminary results which indicate that some of the findings in the original report are being verified through a review of medical records on all births. An increase in birth defects and neonatal deaths among Ranch Hands compared to controls may be substantiated. Although an increased risk for birth defects has been of concern to Vietnam Veterans for some time, the present report purports to review findings from the Baseline Morbidity Report in the light of _a priori_ hypotheses based on the scientific literature. There is no biological basis for expecting an increase in all birth defects following male exposures to chemicals. Thus, like an increase in skin cancer, a significantly increased risk for birth defects and neonatal deaths among Ranch Hand personnel would not be expected from _a priori_ hypotheses based on scientifically sound biological knowledge.

4. Neurological Findings - A negative finding for neurological symptoms is probably expected considering the time since exposure of Ranch Handers.

5. Psychological Assessment - It is not possible to assess the relevance of this section in the report. There were a number of statistically significant differences in scores for sub elements of the Cornell Index and MMPI among high-school only educated Ranch Handers indicating presumably adverse effects. Unfortunately, neither the original Baseline Morbidity Report nor the present report can interpret these in terms of any hypotheses relating to herbicide exposures. It is not clear why this section was included in the present report at all.

6. Hepatic Examination - Several indications of hepatotoxicity associated with dioxin exposure have been observed in both animals and humans. Ranch Hands have experienced significantly more unexplained liver disorders than com-

parisons, and apparently show more sensitivity to alcohol damage. The original report indicated these and other findings, but dismissed them because they did not show a dose effect based on the exposure index which had been developed. The present report quite properly includes possible liver damage as an indicator of herbicide effects with an a priori hypothesis.

7. Dermatological Findings - Chloracne-related skin lesions were not significantly different for each group, and dermatological abnormalities were identical. This had been reported extensively in the original Baseline Morbidity Report.

8. Cardiovascular System - Previous information has suggested that arteritis and atherosclerosis are possibly associated with dioxin exposure, so these and associated clinical conditions should be considered as consistent with a priori hypotheses of possible Agent Orange effects. The finding of significant peripheral pulse deficits among Ranch Hands can be an early indication of arteritis and atherosclerosis. However, it was also noted in the original report that verified heart disease itself was not more prevalent among Ranch Hands, and the excess peripheral pulse deficits were confined almost exclusively to Ranch Hands over 40 years old without a history of cardiovascular disease. Thus, it is not clear which hypothesis this finding is consistent with - abnormal peripheral pulses are not a disease, but may be a sign of any condition causing obstruction of normal arterial blood flow including atherosclerosis which is a risk factor for heart disease.

9. Immunological Effects - Although previous evidence would suggest immunologic deficits among persons exposed to many toxic chemicals, including dioxin, the tests done during the AFHS showed no significant differences between Ranch Hands and controls.

10. Endocrinological Effects - The present report indicates that Ranch Hands had elevated testosterone levels as would be expected from experiments with TCDD treated rat liver, but the difference from comparisons was not statistically significant. They also had a significant "tendency toward hyperthyroxemia which is directionally opposite to what would be expected on the basis of subacute animal studies." (Cited from the original Baseline Morbidity Report, p. XVI-6-12). Thus, on balance the endocrinological results are inconsistent with a priori hypotheses on a herbicide effect.

11. Mortality - The present report suggests that an increased mortality from exposures to dioxin might be expected among Ranch Hands. This is not supported by previous data on acute effects of TCDD in humans, so the failure to find any increased mortality among Ranch Hands is not inconsistant with expectations.

Conclusion - The present report states that eleven clinical areas have been selected because the literature suggested certain effects in a dioxin exposed group. I suggest that two of these, i.e., increased weight loss and mortality should not have been expected in a group of Ranch Hand personnel at this time. Of the remaining nine clinical areas, there were six with statistically significant results. However, in one of these, i.e., increased birth defects, the expectation from the literature would include only: an increase in single gene defects, which was not reported on; an increase in infertility, which was not found; or an increase in chromosomal non-dysjunction leading to aneuploidy, of which there were more cases among the comparisons.

In another clinical area, increased neoplasms, only certain neoplasms should have been expected, i.e. soft tissue sarcomas, lymphoreticular sarcomas, and stomach cancer. Since none of these were detected, the increase in neoplasia seen among Ranch Hands is not consistant with expectations based on previous scientific evidence.

In yet another of the six areas with statistically significant results, i.e., psychological changes, no evidence has been presented, either in the present or in the original Baseline Morbidity Report, that the changes which were found would be expected from herbicide exposure.

That leaves three clinical areas with expected effects, two of which showed results consistent with those expected following dioxin exposure, and one in the opposite direction. Although two out of nine is less dramatic than five out of eleven, it does indicate the possibility that Ranch Hands are different in ways which are detectable as physiological changes, and, that some of these changes may be due to exposures to herbicides. Several of the important results of the study, i.e., an increase in neoplasia of the skin and birth defects as well as neonatal deaths among Ranch Hands and their families, while not logically attributable to dioxin exposure at present, are indications of real differences in the health of Ranch Hands and their comparisons. It should be noted that both the present report and the original Baseline Morbidity Report neither ascribe nor exonerate the observed group differences to an effect of dioxin.

Comments - It is unclear why the present report was written since it does not differ in any sustantial way from the original report, except by implication. By its nature and organization, the present report implies that the results so far can more easily be interpreted as indicating a causative role for Agent Orange in producing potentially serious health effects among exposed veterans.

The only serious challenge to the study is that the exposure index which was developed, and on which any estimate of dose effects must depend, may be grossly inacurrate. What is mysterious is why comments on the Baseline Morbidity Results should matter at this time since the first follow-up report has already been completed and a good laboratory method to determine exposure levels is readily available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date April 17, 1988

From John F. Young, Ph.D.
Executive Secretary, AOWG Science Panel

Subject Review of USAFSAM-TR-88-3

To Ronald W. Hart, Ph.D.
Chairman, AOWG Science Panel

The following comparisons were made for the various subgroups:

1) General Health - weight loss; No differences in body fat.

2) Neoplasia - relative risk = 1.97 (What was SD? or range for OR?) - Neither skin or systemic cancer correlated with herbicide exposure levels (#s were small!)

3) Reproduction - birth defects - no differences in sperm count or % abnormal sperm - 14 indices with 1 comparison (birth defects) with $p < 0.04$; Question: Why is the p value so different between "Learning disability" at 0.19 and "Birth defects" at 0.04 when the numbers involved are nearly identical (page 14, Table 7)?

4) Neurological status - no statistically significant group differences (3 comparisons).

5) Psychological status - Indices developed -> fatigue, anger, mental erosion, anxiety, isolation, and depression -> all showed Ranch Hands to be statistically significantly less well than comparisons. NO data presented!

6) Hepatic function - no obvious group differences - 3 covariable differences -> SGOT-alcohol slope, LDH-alcohol slope, and coproporphyrin-alcohol slope; no variable showed a meaningful relationship with the herbicide exposure index (14 comparisons).

7) Dermatological findings - chloracne - no active chloracne; no significant group differences (7 comparisons): NOTE: Table 12, page 21 is clear and concise which included p value, relative risk, and 95% CI. It would be nice if all of the tables were laid out like this one.

8) Cardiovascular conditions - no significant group differences - subgroup differences of pulses in non-black group ($p = 0.05$) - (hard to tell how many comparisons were made).

9) Immunological competence - no statistically significant difference (12 comparisons).

10) Hematopoietic status - listed on page 7, but no discussion or data in the text.

11) Renal function - listed on page 7, but no discussion or data in the text.

12) Pulmonary function - listed on page 7, but no discussion or data in the text.

13) Endocrine function - significant difference in T3 uptake and 2 hr glucose levels; text indicated that their were 3 differences but several lines later indicated that testosterone levels indicated a non-significant trend (10 comparisons).

14) Mortality - no significant findings.

ABSTRACT: "... Dioxin cannot be confidently identified as the causative agent of these findings at this time because of several reasons, including the absence of correlations with an exposure index and the incomplete clinical picture. However, dioxin is not exonerated ..." THESE ARE TRUE STATEMENTS.

There is some confusion in my mind as whether it is 11 (Abstract), 13 (page 7) or 14 (combined) clinical areas examined.

There needs to be more discussion about what these "significant" findings mean in relationship to those which are "non-significant".

Of the 190 variables examined, the author reported 9 individual comparisons which were statistically different or 4.7%; you would expect 5% by chance alone at the 95% confidence level.

John F. Young, Ph.D.

[Enclosure Question 3e]

THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 9

The Honorable Alan Cranston
Chairman
Committee on Veterans Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in reply to your letter of September 6, 1987, requesting that the Science Panel of the Agent Orange Working Group, review and comment on the Veterans Administration study entitled, "Proportionate Mortality Study of Army and Marine Corps Veterans of the Vietnam War".

The Science Panel met on September 14, 1987, to review and comment on the study. I am appending the summary report from Dr. Ronald Hart, Director, National Center for Toxicological Research, who chairs the Science Panel, and in addition, the individual comments of key members of the Science Panel.

I believe the specific findings discussed in the report which warrant follow up investigation and analysis are clearly identified.

Should you have further questions, please do not hesitate to ask.

Sincerely,

Don M. Newman
Chair
Domestic Policy Council
Agent Orange Working Group

cc: Dr. Ralph Bledsoe, DPC
Dr. William Graham, OSTP
Mr. Gary Bauer, OPD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Phone: (501) 541-4000
(FTS) 540-4000

National Center
For Toxicological Research
Jefferson AR 72079

September 8, 1987

The Honorable Don M. Newman
Chairman, Domestic Policy Council
Agent Orange Working Group

Review of VA submission to JAMA
"Proportional Mortality Study of Army and Marine Corps Veterans
of the Vietnam War"
by P. Breslin, H.K. Kang, Y. Lee, V. Burt, and B.M. Shepard

Summary prepared by

Dr. Vernon Houk & Staff at CDC,
Dr. Donald Barnes & Staff at EPA,
Dr. Marilyn Fingerhut at NIOSH, and
Dr. Ronald W. Hart & Staff at NCTR

This proportionate mortality ratio (PMR) study appears to be well executed in mechanics. However, the presentation and discussion of the results do not provide the necessary caution in interpretation but do allow uninitiated to make causal inferences where they may not exist.

PMR studies are usually used to generate, not test hypotheses. The article appropriately recommends further work to evaluate causal factors.

This study can not be used to infer anything about Agent Orange or any other specific cause of effect other than being a Vietnam veteran.

The authors emphasize only the statistically significant positive findings. From this study the Marines have an increased risk due to Non-Hodgkins Lymphomas and lung cancer; however, the risk of death from genitourinary disease and all cancers combined is statistically significantly decreased.

No evaluation of latency is presented for lymphoma or lung outcomes. An evaluation of time-to-tumor data should be conducted.

The findings for lung cancer in Marine Vietnam veterans are provocative, although similar observations were not made in other studies of Vietnam veterans. The absence of smoking histories makes the interpretation of this finding difficult.

It is not surprising to encounter the small number of statistical departures from expected mortality seen in this study. Some of these could have arisen by chance alone. This study, as originally designed, cannot conclusively clarify mortality risks for Vietnam veterans, let alone elucidate possible causative factors within, or outside of, the Vietnam experience.

Ronald W. Hart, Ph.D.
Chairman, AOWG Science Panel

2

Summary of Review of VA submission to JAMA
"Proportional Mortality Study of Army and Marine Corps Veterans of the Vietnam War"
by P. Breslin, H.K. Kang, Y. Lee, V. Burt, and B.M. Shepard

Summary prepared by
J.F. Young, D.W. Gaylor, R.L. Kodell, and J. Chen
National Center for Toxicological Research
Jefferson, Arkansas 72079
September 8, 1987

- Regardless of any possible methodological flaws, this study can not be used to infer anything about Agent Orange or any other specific cause of effect other than being a Vietnam veteran.
- From the write up, one can not check the statistical procedures and therefore must assume that it was done correctly using acceptable methods; however, a more detailed description of the methods with references would be helpful.
- From this study the Marines have an increased risk due to Non-Hodgkins Lymphomas; however, the Army risk is lower than expected but not significantly. When combined, the overall risk is less than expected with a PMR ~ 0.95.
- The manuscript is for the most part written clearly; however, there are still obvious errors and statements made that are not well documented. Positive findings are pointed out but corresponding negative findings are not discussed.
- Statements are made on page 14 that PMR values may be inflated or deflated. Life-table analyses could be conducted to overcome these limitations.
- It is not clear how age and race adjustments were made in the analyses. Were the average age of the Vietnam and non-Vietnam groups the same?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date · September 11, 1987

From Director
Center for Environmental Health and Injury Control

Subject Review of VA Mortality Study

To Ronald W. Hart, Ph.D.
Director
National Center for Toxicological Research

The Veterans Administration (VA) has conducted a proportionate mortality study (PMR) of 24,235 deaths among U.S. Army and U.S. Marine male veterans who served in Vietnam and 26,685 deaths among male veterans of the same two services who did not serve anywhere in Southeast Asia. All deaths were identified from the VA BIRLS file and occurred between July 4, 1965, and March 1, 1982. These deceased veterans had to have served in the military sometime between July 4, 1965, and March 1, 1973. Career and non-career, officers, and enlisted men, as well as reservists, were included. In-service deaths occurring before 1974 and men dying from war-related injuries were excluded. In service deaths after 1973 were included.

Within the group of Vietnam veterans, the fraction of all deaths attributable to a particular cause was computed and compared to the corresponding proportion for non-Vietnam veterans. The comparison was done using the proportionate mortality ratio (PMR) technique in which age at death, race, and branch of service were taken into account. There was no adjustment for calendar year of death or rank. Altogether, PMRs were computed for 18 major cause of death groupings and for 23 specific cancer sites.

We will address our concerns in data collection, data analysis, and interpretation.

Data Collection. Are the BIRLS tapes truly at least 94 percent complete? From the CDC Mortality Study which used multiple sources of mortality we found that BIRLS was less complete.

Data Analysis. Why do the authors emphasize only the statistically significant positive findings? Why were not the significant decreases in deaths from genitourinary diseases (Table 3) and the decrease in deaths from all cancers for one-tour of duty veterans (Table 5) not discussed?

The lack of association between service in Vietnam and suicide needs to be reevaluated in light of the CDC finding that they were increased only in the first 5 years after discharge. CDC used the time period since discharge rather than year of death. This subject was repeatedly brought up with the VA prior to completion of their analysis. The CDC study would indicate that grouping by 10 year periods would minimize the effect.

The findings for lung cancer and NHL in Marine Vietnam veterans are provocative, although similar observations were not made in other studies of Vietnam veterans. The absence of unusual mortality from soft-tissue cancers is consistent with some previous studies but at variance with others. Because so many statistical tests were done on the data set, these apparent findings could be due to chance. It would be helpful to see a more detailed analysis in which mortality from these cancer sites is examined by calendar year in Vietnam, rank, MOS, and principal duty. These additional analyses would help in deciding whether some factor related to the Vietnam experience is responsible for the apparent association.

Interpretation. The authors suggest that these were major differences in the findings of previous studies cited, but there are in fact few major differences in the findings.

Referenced studies were not critically discussed. There has never been, for example, an association demonstrated between lung cancer and phenoxy herbicides except in the Zack Study (Ref. 29) where 3.6 cases were expected and 6 were found in those exposed to 2,4,5-T. Those authors state that they cannot evaluate trends in lung cancer deaths as they relate to occupation because of "limitation in the data."

As noted above, it is not surprising to encounter the small number of statistical departures from expected mortality seen in this study. These could easily have arisen by chance alone. This study, as originally designed, cannot conclusively clarify mortality risks for Vietnam veterans, let alone elucidate possible causative factors within, or outside of, the Vietnam experience. Reasons include lack of a defined population-at-risk, incomplete ascertainment of deaths, and absence of "exposure" data on individual veterans.

This PMR study appears to be well executed in mechanics. However, the presentation and discussion of the results do not provide the necessary caution in interpretation and allow the uninitiated to make causal inferences where they do not exist.

Vernon N. Houk, M.D.
Assistant Surgeon General

Comments on "Proportionate Mortality Study of Army and Marine Corp Veterans of the Vietnam War" by P. Breslin *et al.*

Marilyn Fingerhut
September 6, 1987

- Use of BIRLS for a PMR study is reasonable.

- Structure of PMR study is reasonable: Random sample of complete file of BIRLS, with Vietnam exposure confirmed; death certificates obtained (96.9% followup), adequate size (at least for Army).

- PMR studies are usually used to generate, not test hypotheses. The article appropriately recommends further work to evaluate etiological factors. The media reports have not conveyed this information.

- The problem at hand results from the timing of the release of the article, and the inclusion of a sentence in the Abstract (inappropriately) referring to Agent Orange exposure.

- The structure of the study is appropriate; the scientific weakness of the article lies in the analysis and interpretation of the results. The authors can revise the article for submission to a journal.

- The weakness of the article results from 1) the absence of data evaluating elevations in other smoking related diseases in the Marines, 2) absence of latency evaluations for the malignancy outcomes, 3) lack of data evaluating the adequacy of the marine comparison group, and 4) inadequate evaluation of the limitations of the PMR study design.

- No evaluation of latency is presented for lymphoma or lung outcomes. Service was '64-'73, deaths were '65-'82. The article does not evaluate the relationship of time of exposure to time of death.

- No data are provided to show whether other circulatory or respiratory deaths were elevated in army and marines for conditions associated with smoking.

- It is unclear whether the cancer outcomes were obtained in the overall PMR, or in a separate Proportionate Cancer Mortality Ratio (PCMR).

- The results for deaths from external causes and accidental poisonings are consistent with other studies of veterans and point out problems for veterans following this war.

- The nonVietnam comparison group for the Army is large, so the numbers can be expected to be stable; the same may not be true for the marines. It would have been helpful if, 1) the authors had carefully presented data to show that the marine Vietnam vs. nonVietnam populations were truly comparable, and 2) the authors had provided a table showing the expected numbers for each cause of death if the national population had been used as the comparison.

7/17/87

#5

REVIEW OF VIETNAM VETERANS MORTALITY STUDY

A study of proportionate mortality among U.S. Army and Marine veterans who served between July 4, 1965 and March 1, 1973 and died before March 1, 1982 was reported by the Veterans Administration. The study included 19708 Army and 4527 Marine veterans who had served in Vietnam and 22904 Army and 3781 Marine veterans who had not served in Southeast Asia during tis period. The study included a random sample of about one-third of the potentially elligible veterans who had died during this period. The selection of study subjects and recovery of information on them appears to have been unbiased and appropriate.

The major findings from this study included a statistically significant excess of accidental and drug related deaths and paucity of suicides among Army veterans who had served in Vietnam compared to those who had not served in Southeast Asia. In addition, there was a statistically significant excess of lung cancer and non-Hodgkins lymphoma among Marine veterans who had served in Vietnam compared to those who had not. Several other findings were not mentioned in either the conclusions nor in the narrative, but are evident in the tables. These include a statisically significant decrease in mortality due to genitourinary diseases and cancer of the extra-cranial nervous system among Army Vietnam veterans. In addition, there appears to have been a signifcant decrease in cancer deaths among enlisted Army veterans with only one tour of duty in Vietnam, and among similar Marine veterans before 1975. There was also a significant increase in accidental poisonings among enlisted Marine Vietnam veterans dying before 1975.

The authors computed Standardized Proportionate Mortality Ratios (SPMR) and tested with the Chi-Square statistic (not presented in the tables). According to the reference used to justify this procedure (ref # 13), Professor Monson suggests using the Poisson approximation of the variance of the expected deaths, i.e., that the expected number of deaths approximates the variance. If this procedure is applied to the information which can be deduced from the observed number of deaths and the SPMR as given in the tables, several additional SPMRs appear to be statistically significant. These include an excess of all cancer deaths among Marine veterans who served in Vietnam, particularly single tour enlisted Marines after 1975. Other possibly significant findings would include a decrease in deaths due to infectious diseases and diseases of the blood, an increase in deaths due to musculoskeletal and connective tissue diseases, and a decrease in deaths from thyroid cancer and non-Hodgkins lymphoma among Army Vietnam veterans.

While there is no way to determine which statistical procedures are "correct", these results indicate that more significant findings are available in these data than have been dicussed in the manuscript. While this does not make it any easier to interpret the results, it does serve to point out the selective nature of the findings which have been emphasized in the manuscript. In particular, the inclusion of one-seventh of the abstract and considerable dicussion in the narrative to Agent Orange is misleading. Other possible explanations for the findings should receive relatively more emphasis.

Carl A. Keller

Carl A. Keller, Ph.D.
Epidemiologist, NIEHS

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9/8/87

COMMENTS ON "PROPORTIONATE MORTALITY STUDY OF "ARMY AND MARINE CORPS VETERANS OF THE VIETNAM WAR"

Donald G. Barnes
U.S. Environmental Protection Agency

1. Proportionate mortality studies have inherent limitations which restrict their interpretation and conclusions; e.g., reduced PMR in one area necessitates increased PMR in another area. This particular study is a generally well-designed example of this type of investigation. The report clearly discusses the procedures, methods of analysis, and the conclusions, including caveats. The results should not be cited without an thorough appreciation of these caveats.

2. The study is a descriptive study which essentially suggests hypotheses for further investigation. As such, the study does not test any particular association, let alone prove any cause-effect relationship.

3. It should be noted that of all the PMRs the two identified as being of concern, while statistically significant, are modest (roughly 2) -- a tribute to the scale of the study.

4. Among the areas of concern is the question of whether there is an inherent difference between Marines in Vietnam, compared to non-Vietnam Marines and all Army troops. It has been suggested that the Marines in Vietnam had attitudes and behaviors (e.g., risk takers) which were distinguishable from other troops.

5. The diagnosis of Non-Hogkins lymphoma is not easy. There might be a bias in the recording of this diagnosis in cases in which it was known that the patient had served in Vietnam.

6. If one is concerned about the etiology of cancer vis a vis Vietnam, it would be preferable to exclude any cancers that appear prior to some minimal latency period; e.g., 10 years.

7. It would be enlightening to look at the proportionate cancer mortality ratios (PMCRs), which would examine the relative cancer experience in greater detail.

8. Possible followups include:
    a. An I Corps study of the Army veterans -- planned
    b. A periodic updating of the current study to take into account latency, etc. -- planned?
    c. A cohort study of the Marines
    d. A case-control study of the NHL and lung cancers in the Marines.

The question of exposure still remains. Given the recent results of the CDC exposure validation study, it is not clear that options c and d are tenable.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 17 1988

OFFICE OF
THE ADMINISTRATOR

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510-6375

Dear Mr. Chairman:

Enclosed for insertion in the hearing record are EPA's responses to questions you forwarded in your June 2 and June 6, 1988 letters following the May 12, 1988 hearing on Agent Orange-related issues.

Please feel free to contact us if we can be of any further assistance.

Sincerely,

Donald G Barnes

Donald G. Barnes
Acting Director
Science Advisory Board

Enclosure

EPA'S RESPONSES TO FOLLOW-UP QUESTIONS FOR MAY 12, 1988 HEARING ON AGENT ORANGE-RELATED ISSUES

FORWARD

Throughout the questions below (and also in the hearing) reference is made to "dioxin." In most, but not all instances, "dioxin" is used as a shorthand for 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD).

The chlorinated dibenzo-p-dioxins (CDDs) are a family of 75 related chemicals, some of which are quite toxic in standard laboratory test systems. Of particular note and well-earned notariety is 2,3,7,8-TCDD, experimentally the most potent of the CDDs and essentially the only member of the CDD family found in 2,4,5-T (which comprises 50% of Agent Orange).

Because of the somewhat ambiguous nature of the shorthand term, "dioxin", I have couched my responses explicitly in terms of 2,3,78-TCDD.

FOLLOW-UP QUESTIONS FROM SENATOR CRANSTON

Question 1

"Please evaluate the written testimony (copy enclosed) submitted by Dr. Thomas Gasiewicz, who testified at the Committee's May 12 hearing on behalf of the Vietnam Veterans of America."

Response to Question 1

I agree with what I understand to be the thrust of Dr. Gasiewicz's comments; namely,

a. Ideally, risk assessment would be based on human data.
b. In the case of 2,3,7,8-TCDD, the human data base is not sufficient to generate a definitive risk assessment.
c. In the absence of such data, information from animals should be used.
d. More definitive information may be forthcoming when "exposed" populations are more accurately characterized through the analysis of 2,3,7,8-TCDD in their tissues.

I am somewhat more hopeful than Dr. Gasiewicz that current studies in humans (especially the NIOSH Dioxin Registry Study, referred to by Drs. Mason and Houk in their testimony) will shed some light on the sensitivity of humans to carcinogenic and immunological effects of 2,3,7,8-TCDD.

In regard to specific statements made by Dr. Gasiewicz, I generally agree with his observations. However:

a. There are statements stemming from certain references which have not yet been published; and, therefore, I cannot comment on those statements.

b. It should be noted that the field of immunology is in the process of maturing and the use of immunotoxicity as an endpoint in risk assessment is even more recent. The signficance of an observed change in immunological parameters is not always clear, especially when those changes are observed in vitro. Further research is appropriately continuing to clarify these matters.

c. While "dioxin" (2,3,7,8-TCDD) has indeed been shown to be carcinogenic in "all" lifetime animal feeding studies yet performed, it should be noted that these studies are limited in number and have been confined to different strains of rats and mice. The Agency has taken the position that this information can be extrapolated to obtain an upper bound estimate of the risk to humans.

d. I certainly agree that the Ah receptor is an important factor in the expression of toxicity of 2,3,7,8-TCDD. However, there are sufficient data to indicate that the simple presence of the receptor is a "necessary, but not sufficient, condition" to result in manifest toxicity.

e. In addition to the Kahn et al study cited by Dr. Gasiewicz, I would cite the recent CDC study (cf. Dr. Mason's testimony) on the body burden of 2,3,7,8-TCDD in veterans "likely to be exposed" vs. those "less likely to be exposed," in which there was no significant difference between the 2,3,7,8-TCDD levels in the blood of the two groups. Some of Dr. Kahn's subjects who had high body burdens also had atypical exposure scenarios. In fact, Dr. Kahn's data can be viewed as supporting the notion that the Ranch Hand personnel were significantly more highly exposed than general ground troops. This information reenforces the notion that the best study subjects are likely to be the Ranch Hand cohort and the Dioxin Registry cohort.

Question 2A

"In written testimony for the Committee's May 12 hearing (page 4) the Environmental Protection Agency (EPA) states that in 1986 it began to reassess its position on the carcinogenicity of dioxin, taking into account several factors, including 'recent data that suggest a "background level" of "dioxins"...in the tissue of humans living in industrialized societies around the world.' Please explain what is meant by that statement, and describe what the EPA found in this respect."

Response to Question 2A

Recent investigations of 2,3,7,8-TCDD and related compounds in human tissues (primiarily blood and adipose tissue) strongly suggest that members of the general population in industrialized societies are being exposed to low levels of these chemicals. A likely route of exposure is via the food chain. The originating source(s) of the contaminants has not been identified, although several candidates have been suggested; e.g., municipal waste combustion and previous pesticide use.

Question 2B

"According to your written statement, the EPA also considered, in reassessing its position on dioxin, 'the apparent discontinuity between estimated human risks, projected from animal experiments, and the effects observed in human populations....' How significant is that discontinuity, and what did the EPA conclude from it?"

Response to Question 2B

2,3,7,8-TCDD is often referred to as "the most toxic manmade chemical," and yet clear evidence of human toxicity as a consequence of exposure to the chemical has been generally been limited to a chloracne -- a persistent (possibly disfiguring) skin condition -even in situations of accidental high exposure (cf. industrial accidents) and from low level chronic background exposures. This apparent discontinuity has suggested to some that humans may not be as sensitive to the effects of 2,3,7,8-TCDD as are animals.

The Agency's reassessment has not resolved this question.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

JUN 2 2 1988

The Honorable Alan Cranston
Chairman, Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510-6375

Dear Mr. Chairman:

This is in response to your letter of June 3 requesting answers to follow-up questions from the May 12 hearing on Agent Orange issues. Our answers are enclosed.

We appreciate your interest in the health of Vietnam veterans.

Sincerely yours,

James O. Mason

James O. Mason, M.D., Dr.P.H.
Assistant Surgeon General
Director

Enclosure

Answers to Follow-up Questions for May 12, 1988, Hearing on Agent Orange Legislation and Oversight Issues from Senator Alan Cranston, Chairman, Committee for Veterans' Affairs, to the Centers for Disease Control

1. Question:

   Please evaluate the written testimony (copy enclosed) submitted by Dr. Thomas Gasiewicz, who testified at the Committee's May 12 hearing on behalf of the Vietnam Veterans of America.

   Answer:

   Dr. Gasiewicz's basic premise is that the results of studies on experimental animals should be taken into account in evaluating the potential health effects of dioxin in humans. There is little argument with this suggestion, and animal data have played an important role in pointing out the sorts of health effects that should be evaluated in studies of humans who have been potentially exposed to dioxin. It is not clear if Dr. Gasiewicz proposes that animal data be used beyond this scope and be relied upon to establish actual health effects in humans. If this is the case, there would be less agreement.

   The overall findings in different animal species are not as consistent as the few examples selected by Dr. Gasiewicz. In different animal species, the toxicity of dioxin, in terms of dose and toxic effects, varies a great deal. Therefore, the Review Committee of the American Academy of Clinical Toxicology concluded that extrapolation of findings in animals to humans would lead to tenuous predictions (Clinical Toxicology 1985;23:195).

   The main reason Dr. Gasiewicz gives for the need to rely on animal data is that human studies have been flawed by lack of data on amount of exposure and inadequate measurement of sensitive indicators of toxic effects. The recent development of a highly sensitive serum dioxin assay and its use in comprehensive health studies of people exposed to dioxin overcome these limitations. The evaluation of a number of sensitive health measures relative to serum dioxin level in the Ranch Hand Morbidity Study and the National Institute for Occupational Safety and Health study of phenoxyherbicide production workers should go a long way toward resolving the issue of human health effects of dioxin.

2. Question:

   Is the Centers for Disease Control (CDC) considering reducing its assessment of the carcinogenicity of dioxin, especially in light of the proposed recent reduction by the Environmental Protection Agency? If so, what evidence supports such a decision?

Answer:
Yes. CDC's original cancer risk assessment of dioxin was based upon data from the late 1970's and early 1980's. The CDC concluded that a level of concern in residential soil (people living from birth through 70 years) was 1 part per billion 2,3,7,8-TCDD. This assessment was based upon animal data, principally the Kociba study. Since then, new data have become available suggesting that in humans 2,3,7,8-TCDD exposure may not result in the same effects seen in the most sensitive species. The CDC is collecting all of the studies and will, with the advice of nongovernmental scientists, determine whether our previous recommendation is still valid or if a different level should be set.

3. Question:
What steps could the CDC take -- and how much time would be saved -- to accelerate completion of the Selected Cancers Study if increased funding from the canceled Agent Orange Study or from other sources were provided for that purpose? Please specify the amount of time which would be saved by each such step.

Answer:
The completion of the Selected Cancers Study is primarily dependent on the ascertainment of the cancer cases. Nothing can be done to "accelerate" the occurrence of these cancers. The other study activities (interviews, histology reviews, data analysis) are currently on as tight a schedule as possible, while allowing for the peer review and publication requirements necessary for scientifically credible results. Accordingly, additional funding will not reduce the time frames for the completion of this study.

4. Question: (A)
Does blood dioxin analysis reveal anything other than the amount of dioxin exposure; that is, can it determine the date of exposure or the kind of dioxin compound to which there was exposure, or distinguish between military and civilian exposure?

Answer:
Blood dioxin analysis measures the amount of dioxin in the blood. It cannot determine the date the exposure occurred. The compound referred to commonly by the name of dioxin is 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). Compounds which are in the same family of compounds as 2,3,7,8-TCDD are called "dioxin congeners." Examples of dioxin congeners are 1,2,3,7,8-pentachlorodibenzo-p-dioxin (1,2,3,7,8-PCDD) and 1,2,6,8-tetrachlorodibenzo-p-dioxin. When measuring for dioxin congeners in the blood, we can distinguish between the different dioxin congeners; so, for example, we can distinguish between 2,3,7,8-TCDD and 1,2,3,7,8-PCDD. Therefore, if a person had been exposed to one of the dioxin congeners, we would be able to distinguish that exposure from exposure to another dioxin congener.

It is not possible at this time reliably to distinguish between military and civilian exposure by measuring dioxin congeners. The dioxin congener which was present in Agent Orange was 2,3,7,8 TCDD. There is some suggestive evidence that different types of exposures lead to different patterns of dioxin congeners (sometimes called fingerprint patterns). However, the specificity of these serum patterns of dioxin congeners has not yet been verified across a variety of civilian exposure situations. This verification across a variety of civilian exposure situations must be completed to assure that a dioxin congener pattern is unique to any type of military or civilian exposure. The CDC is currently examining dioxin congener patterns in some occupationally exposed workers, which will provide additional information in this area.

Question: (B)

Can this or another blood analysis be used to trace exposure to other herbicides, such as 2,4-D, another component of Agent Orange?

Answer:
2,4,-D is a polar compound which is excreted from the body within weeks after the exposure. Blood analysis for this compound would not be able to detect any exposure that occurred in Vietnam.

5. Question:
Senator John Kerry, in his written statement for the Committee's May 12 hearing (which he inserted in the Congressional Record on May 13 [copy enclosed]), described a number of Agent Orange-related studies. Please provide your assessment of his description of and conclusions drawn from each study, as well as his overall conclusions regarding the effects of Agent Orange. In your answer, please list each study and follow with your individual evaluation.

Answer:
Senator John Kerry's overall conclusions regarding the effects of Agent Orange are based on data from about one dozen epidemiological studies. The studies cited by Mr. Kerry fall into three general categories: (1) studies of U.S. Air Force personnel who were engaged in the aerial spraying of herbicides in Vietnam (i.e., Ranch Hand Study): (2) studies involving groups of Vietnam veterans other than Ranch Hands; and (3) studies involving agricultural and forestry workers who handled herbicides as part of their employment.

The Ranch Hand studies are not relevant to the vast majority of Vietnam veterans since many Ranch Hand personnel had recognized heavy exposure to Agent Orange, while the average U.S. Army combat veteran in Vietnam does not appear to have been heavily exposed to Agent Orange based on the CDC

Agent Orange Validation Study. The studies of non-Ranch Hand Vietnam veterans are of little relevance to the Agent Orange issue since there is no documentation of actual exposure to Agent Orange in these studies that would permit subdivision of the total study group into subgroups denoting a gradient in exposure. Some of the cited studies of Vietnam veterans involve small numbers of cases of specific diseases that preclude drawing firm conclusions. Also, Mr. Kerry has reported almost any instance where the Vietnam study group experienced an increased incidence of some health outcome compared to other veterans, no matter how small and inconsequential the actual numbers were and whether or not the difference between the two groups was statistically significant. This highly selective use of study results does not support a conclusion one way or another on any issue. The studies of agricultural and forestry workers are not applicable to Vietnam veterans (at least non-Ranch Hand) because the former groups consisted of herbicide sprayers and handlers whose exposures would have been much higher than those of the average Vietnam veteran.

6. Question:
Admiral E.R. Zumwalt, Jr., testified at the May 12 hearing that "[i]f you take the logistics personnel of the Navy, you had 110 times as many lymphomas and 58 times as many lung cancers. With regard to the Vietnam Experience Study . . . in comparing the Vietnam veterans to the non-Vietnam veterans, there were 80 percent more who suffered low sperm, 29 percent more who had fertility problems, 135 percent more who had psychological problems, 49 percent more who had alcohol problems, 45 percent more who had skin disorders, and 31 percent more who had children with birth defects. . . ." Please evaluate and comment on each of the statistics which Admiral Zumwalt cited.

Answer:
In discussing the statistics presented by Admiral Zumwalt, it is important to explain where these data came from and to what groups of veterans they apply.

The "110 time as many lymphomas" refers to an increase of 110% in the proportion of deaths due to non-Hodgkin's lymphoma among Marine Vietnam veterans relative to Marines who served elsewhere. Similarly, the "58 times as many lung cancers" refers to an increase of 50 percent in the proportion of deaths due to lung cancer in Marine Vietnam veterans relative to Marines who served elsewhere. These findings did not apply to the Army Vietnam veterans in this study. Without additional information on these veterans (e.g., smoking histories), it is not possible to explain the reasons for these findings. We understand that the Veterans Administration is trying to obtain additional data which might help explain the results of this study.

We believe the statement "80% more who suffered low sperm" refers to the low sperm concentration findings of CDC's Vietnam Experience Study. Actually, in this study Vietnam veterans were twice as likely to have low sperm concentrations compared with the non-Vietnam group. The reason for these differences in sperm characteristics is not clear, and the Journal of the American Medical Association (JAMA) articles contain a complete discussion of this issue. The sperm differences did not have an influence on the number of children fathered or on birth defects.

The "29% who had more fertility problems, 45% more who had skin disorders, and 31% who had more children with birth defects" represent self-reported information obtained from the veteran during the telephone interview. Although Vietnam veterans reported more problems with impaired fertility, both groups of veterans reported fathering the same average number of children. Also, while Vietnam veterans reported more birth defects and health problems among their children, these reports were not verified by information contained in hospital birth records. With respect to skin disorders, there were large differences in reported skin problems, but on examination, all skin conditions, including scars from possible past chloracne were found with similar frequency in Vietnam and non-Vietnam veterans.

We are not sure where the "135% more who had psychological problems" came from. However, the results of the psychological examinations in the Vietnam Experience Study, as well as the other data mentioned above, are fully discussed in the JAMA articles. As highlighted in our testimony, while most men in both the Vietnam and non-Vietnam groups fell within normal limits in these evaluations, current psychological problems (alcohol abuse or dependence, anxiety, and depression) were more prevalent among Vietnam than non-Vietnam veterans. Also, about 15% of Vietnam veterans had reported ever experiencing symptoms which met diagnostic criteria for post-traumatic stress disorder (PTSD), whereas 2.2% had experienced an episode of PTSD as recently as the month before the examination; 20 years after their service in Vietnam.

7. Question:
Senator Tom Daschle, in a supplemental statement (copy enclosed) submitted following the May 12 hearing, discussed his concerns regarding what he termed "discrepancies" between certain testimony at the hearing and reports he had been given on the "status and details of several of the studies covered in the hearing." Please provide your assessment of his statements with respect to:

(A) Question:
The evidence linking dioxin with suppression of the immune system.

Answer:
Senator Daschle is correct in his claim that there is some evidence to suggest an effect of dioxin on the immune system. As noted in his testimony, however, the evidence is not direct, but is indirect. This indirect evidence comes primarily from studies of animals and shows that, in various species, dioxin suppresses or alters immune function. Extrapolation from animals to humans is difficult, because the extrapolation must account for dose, metabolism, and interspecies differences. Although immunosuppression has not been conclusively documented in humans, it is reasonable to speculate from animal studies that, at least at high exposure levels, the human immune system could be affected by dioxin. Unfortunately, it is not known what level of exposure would be necessary to affect human health adversely.

(B) Question:
The National Cancer Institute's study of Kansas farmers and the relevance of the study results to Vietnam veterans' exposure to Agent Orange. Please also comment specifically on each of the possible conclusions which Senator Daschle states can be drawn from that study.

Answer:
The NCI study may be of some relevance to the subgroup of Vietnam veterans who actually sprayed herbicides, but it does not appear relevant to the average Vietnam veteran who most likely did not have heavy exposure to Agent Orange based on the results of the CDC Agent Orange Validation Study.

1. The increase in NHL is unrelated to the 2,4-D/dioxin mixture.

   Comment: This is the least likely conclusion.

2. 2,4-D is the cause of the increase.

   Comment: This is a likely possibility, especially if any non-dioxin contaminants of 2,4-D are included as possible causes.

3. 2,4-D and dioxin worked together to cause the increase.

   Comment: This possibility seems to suggest an interactive effect of two substances. Such a mechanism of action is difficult to assess in this situation.

4. Dioxin is the cause of the increase.

   Comment: This is a possibility although it would mean that dioxin isomers of less toxicity than 2,3,7,8 TCDD are carcinogenic.

(C) Question:
The importance of adjusted analyses, particularly with respect to the Ranch Hand Study.

Answer:
The "adjusted analyses" of the Ranch Hand Study is basically an expansion of the discussion section of the 1984 Ranch Hand Base-line Morbidity Report. This analysis focuses on 11 selected areas of morbidity and on the fact that the herbicide exposure index used in that report was probably quite imprecise. The five "significant" morbidity measures described as being in excess among the Ranch Hand group, are either under-going validation or are not supported by subsequent work. The exposure index issue is also being resolved since the Air Force will obtain serum TCDD levels for use as their criterion of exposure. In summary, this reanalysis does not suggest any new interventions or new directions for the United States Air Force Health Study.

(D) Question:
The Centers for Disease Control's (CDC) Vietnam Experience Study, particularly regarding the findings about birth defects.

Answer:
Senator Daschle's general comments concerned the presentation of results and scrutinizing the positive findings until these findings could be explained away. We believe the JAMA articles represent a balanced presentation of the findings from this study. Our results were peer reviewed on a regular basis and the JAMA articles were reviewed by the Office of Technology Assessment and the JAMA reviewers prior to publication.

With respect to the issue of non-Hodgkin's lymphoma, we have explained that the Vietnam Experience Study was not designed to evaluate the risk for specific types of cancers. This was originally addressed in the study protocol (1983) and is the reason the Selected Cancers Study is being conducted. The CDC is concerned about the non-Hodgkin's lymphoma findings to date and believes close attention should be given to the ongoing studies (e.g., Selected Cancers Study) which will provide additional data in this area.

Senator Daschle also expressed concern about the birth defects data from the Vietnam Experience Study (VES). He states that, for the hospital birth records substudy, "only a small, nonrandom subsample of the birth records were checked," and that there are problems with this approach. He states it would be preferable to (1) verify all birth defects or at least a larger random subsample, and (2) verify birth defects using medical records or examinations instead of hospital birth records.

We believe that Senator Daschle's comment about the size and representativeness of our subsample is misleading. We examined the birth records of over 3,000 children. This substudy was large enough to detect a relative risk of 1.4 for total birth defects. Our findings showed no difference at all between the two cohorts; the relative risk was 1.0. We have no reason to believe that these findings would have been different if the subsample had been larger or that they are, in any way, the result of the size of the sample.

With regard to the representativeness of the subsample, the children included are the children of approximately half of the veterans who completed the physical examination. Detailed analyses of the examination participants relative to the telephone interview participants showed these groups to be very similar. In addition, participation in the birth records substudy was very high in both cohorts, and, moreover, the two cohorts were similar with respect to various demographic and military characteristics. Thus, there is no evidence of selection bias or participation bias in this substudy. We believe that the children in this substudy are representative of all children reported in the interview.

In collecting medical records, we limited the time period to the immediate postbirth interval, as opposed to a longer time period, for three reasons. First, the main purpose of this records study was to use an independent source of data to verify or refute the cohort differences found in the interview data. Our interest was not so much in the absolute validity of the rates of total birth defects, but in the relative validity of the cohort comparison. While those birth defects evident at birth do not represent all birth defects, we had no reason to believe that the comparison of this subset of birth defects between the two cohorts would not be valid. Second, this approach was less subject to potential reporting bias because it relied only on the accurate reporting of time and place of birth. If we had collected medical records for a longer, postbirth, time period, we would have had to rely on veterans' reports of hospitalizations, clinic and physicians visits, and dates, places, and provider names for these services. If the two cohorts differed in their ability or willingness to accurately report such information, the ultimate collection of medical records would be biased. Lastly, it was feasible to collect and analyze birth records for a subgroup of children within the time frame of the other VES study components so that all results could be interpreted and presented simultaneously.

(E) Question:
The CDC's cancelled Agent Orange Study, particularly regarding conclusions drawn from that study about the lack of substantial Agent Orange exposure among ground troops in Vietnam.

Answer:
There are several important points to consider in evaluating the results of the TCDD Validation Study in drawing conclusions about Agent Orange exposure among ground troops in Vietnam. First, the study design of the Validation Study permitted the evaluation of five different military records-based exposure scores, as well as self-reported exposure by the veteran. The "hits" model was not the only method evaluated in this study. There was no association between TCDD levels and any of the records-based exposure scores or self-reported exposure.

Second, the median TCDD level in the Vietnam veterans and non-Vietnam veterans was identical--3.8 parts per trillion (ppt). About 1% (9 veterans) of the Vietnam sample and 3% (3 veterans) of the non-Vietnam sample had current TCDD levels greater than 10 ppt. Two Vietnam veterans and no non-Vietnam veterans had levels above 20 ppt--1 with 25 ppt and another with 45 ppt. The veteran with 45 ppt reported no exposure (military or civilian), and the veteran with 25 ppt reported 180 days of indirect military exposure (defined as walking through or clearing vegetation in a previously sprayed area), plus 1 day of home use of herbicides. Both men reported their health is excellent, with no health problems perceived as a consequence of exposure to Agent Orange.

Third, the 646 Vietnam veterans served an average of 320 days in tactical battalions which operated in the heaviest sprayed area of Vietnam (III Corps) during peak years of Agent Orange spraying (1966-69).

And fourth, at the same time the Validation Study was being carried out, CDC was measuring TCDD levels on a group of Air Force health study participants in the U.S. Air Force and CDC study of the half-life of TCDD. Of the 147 Ranch Handers whose TCDD values were measured, 25 had current TCDD levels between 50-100 ppt, 16 between 100-200 ppt, and 5 over 200 ppt. All but 1 of the 49 veterans in the comparison group had TCDD levels less than 10 ppt.

These data, as well as data from the National Institute for Occupational Safety and Health Pilot Study of Herbicide Production Workers and the New Jersey Pointman Project, show that substantial TCDD levels can be detected in occupationally exposed individuals whose last known exposure occurred 15 to 20 or more years ago. The data also suggest that the average ground troop probably did not have unusually heavy dioxin exposure in Vietnam.

(F) Question:
Government interference in dioxin studies, especially in peer review procedures, and the effects thereof.

Answer:
The CDC has had no interference from other Government agencies regarding the peer review and release of information from its studies of the health of Vietnam veterans.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892
Executive Plaza North
Room 418
(301) 496-9093

June 27, 1988

The Honorable Alan Cranston
Chairman
Committee on Veterans' Affairs
United States Senate
Washington, DC 20510-6375

Dear Senator Cranston:

Thank you for your June 2 and 6 inquiries following the Committee's May 12, 1988 hearing on Agent Orange-related issues. I am pleased to respond for the National Cancer Institute (NCI).

You asked that I evaluate the testimony submitted by Dr. Thomas Gasiewicz, who testified on behalf of the Vietnam Veterans of America. It appears that the toxicological information contained in Dr. Gasiewicz's testimony is accurate, as far as I and others at NCI can determine. However, there is considerable debate throughout the scientific community as to the adequacy of the data to conclude that dioxin is associated with adverse human health effects.

Concerning the question as to whether one should rely on animal data in evaluating possible toxic effects of any compound, I would emphasize that all data should be evaluated. Relying only on animal data can be misleading. Chemicals with toxic effects in animals may pose no risk to humans. Alternatively, animal data may give false assurances of safety, as in the cases of benzene or arsenic. These two materials were linked to cancer in humans, and limits were set on their levels in the workplace despite many animal studies showing no carcinogenic effect.

You asked what diseases fit within the category of "immunosuppressant disabilities." Immunosuppressant disabilities are normally thought to include hypersensitivity reactions, increased susceptibility to viral and bacterial infections, serum sickness, various allergic disorders, urticaria and the like.

You also inquired whether the NCI's 1986 Kansas study of agricultural workers provides any evidence regarding the possible toxic effects of dioxin. Our study did not provide evidence as to possible toxic effects of dioxin for several reasons. The exact batches of herbicides used by the Kansas farmers had not been analyzed for dioxin content. Second, the likelihood of contamination of the major phenoxyacetic acid herbicide used (2,4-D) by 2,3,7,8-TCDD is very small, although other less toxic isomers or dioxins may occur. The carcinogenicity of most of the other chlorinated dioxin isomers is not known, but a mixture of 1,2,3,6,7,8- and

1,2,3,7,8,9-hexachloro-p-dioxin appears to have been tested for carcinogenicity according to accepted protocols.

Senator Daschle asked us about how the dioxins in the Kansas herbicides compare to 2,3,7,8-TCDD as well as whether 2,4-D was primarily responsible for the higher than expected incidence of lymphomas among Kansas farmers. In the NCI Kansas study, the excesses in non-Hodgkin's lymphoma (NHL) were relatively consistently associated with phenoxyacetic acid herbicide use, specifically 2,4-D. Risk increased with several measures of 2,4-D exposure. The few farmers exposed to 2,4,5-T, the phenoxyacetic acid herbicide known to be contaminated with 2,3,7,8-TCDD, did not appear to be at excess risk of non-Hodgkin's lymphoma. It appeared that 2,4-D was more likely to be responsible for the excess levels of NHL than other herbicides, insecticides, or other factors.

I hope this information is useful to you and the other committee members.

Sincerely,

Shelia Hoar Zahm

Shelia Hoar Zahm, Sc.D.
Epidemiologist
Occupational Studies Section
Environmental Epidemiology Branch

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June 23, 1988

The Honorable Alan Cranston
Chairman
Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed are responses to the written questions you sent me following the May 12, 1988 hearing on Agent Orange issues. Two sets of questions, the first from you, accompanying your June 3 letter, and the other through you from Senator Daschle, accompanying your June 6 letter, are included. I hope the responses are helpful in sorting through the many and varied studies of Vietnam veterans that have been carried out over the past few years. As always, I am happy to discuss the technical aspects of these studies further with the committee staff. I would be happy, as well, to discuss the studies with staffers of individual Senators who are involved in veterans' issues, should they so desire.

Thank you again for the opportunity to appear before the Committee to present OTA's views.

Sincerely,

Hellen Gelband

Hellen Gelband
Senior Analyst

enclosures

Follow-up Questions for May 12, 1988 Hearing on
Agent Orange Legislation and Oversight Issues
from Senator Alan Cranston, Chairman, to
the Office of Technology Assessment

1. Please evaluate the written testimony (copy enclosed) submitted by Dr. Thomas Gasiewicz, who testified at the Committee's May 12 hearing on behalf of the Vietnam Veterans of America.

2. Dr. Gasiewicz in his written testimony suggests that, in light of "[t]he consistent findings in all experimental animals yet examined . . ." regarding the toxic effects of dioxin and since "[p]ast studies of exposed humans are of limited use . . . ", we should rely on the animal data. Is the animal data so clearcut, and, if so, does it provide an adequate scientific basis for concluding that dioxin is associated with adverse human health effects?

3. What diseases fit within the category of "immunosuppressent disabilities", a term used in S. 1787?

4. Senator John Kerry, in his written statement for the Committee's May 12 hearing (which he inserted in the

Congressional Record on May 13 (copy enclosed)), described a number of Agent Orange-related studies. Please provide your assessment of his description of and conclusions drawn from each study, as well as his overall conclusions regarding the effects of Agent Orange. In your answer, please list each study and follow with your individual evaluation.

5. Senator Tom Daschle, in a supplemental statement (copy enclosed) submitted following the May 12 hearing, discussed his concerns regarding what he termed "discrepancies" between certain testimony at the hearing and reports he had been given on the "status and details of several of the studies covered in the hearing." Please provide your assessment of his statements with respect to:

(A) The evidence linking dioxin with suppression of the immune system.

(B) The testimony by the Air Force witnesses and the merits of the Air Force Ranch Hand study.

(C) The National Cancer Institute's study of Kansas farmers and the relevance of the study results to Vietnam veterans' exposure to Agent Orange. Please also comment specifically on each of the possible conclusions which Senator Daschle states can be drawn from that study.

(D) The VA's Proportionate Mortality Study.

(E) The importance of adjusted analyses, particularly with respect to the Ranch Hand Study.

(F) The Centers for Disease Control's (CDC) Vietnam Experience Study, particularly regarding the findings about birth defects.

(G) The CDC's cancelled Agent Orange Study, particularly regarding conclusions drawn from that study about the lack of substantial Agent Orange exposure among ground troops in Vietnam.

(H) Government interference in dioxin studies, especially in peer review procedures, and the effects thereof.

Responses to Follow-up Questions for May 12, 1988 Hearing on Agent Orange Legislation and Oversight Issues from Senator Alan Cranston, Chairman, to the Office of Technology Assessment

1 and 2. Dr. Gasiewicz presents an approach to risk assessment. He is certainly correct that animal studies form the basis of many risk assessments carried out around the world, including the risk assessments that led to the initiation of regulatory action against 2,4,5-T. Because 2,3,7,8-TCDD (referred to hereafter as dioxin) is toxic to animals, it is, for public policy purposes, assumed to be toxic to humans. Dioxin is acutely toxic, and in long-term animal studies, has proven carcinogenic at many different sites. It has been shown to affect the immune system in experimental animals. In two-generation studies, dioxin has not been shown to act through the male in affecting birth outcomes. Animal data are used, though never without controversy, to regulate exposures to potential toxic hazards, to prevent the possibility of harm. They cannot be used, however, to predict what will happen to a particular group of human beings who might be exposed to a substance, and certainly not to determine what has been the affect on a group of previously-exposed people. Neither the numbers of people who might be affected, nor the specific medical conditions that might occur can usually be predicted. The reason for undertaking epidemiologic studies of potentially toxic chemicals is to find out whether people have actually been adversely affected by a particular experience, and if so, to estimate the size of the effect.

The presumed usefulness of animal bioassays rests on an assumption that substances found to be hazardous to animals are also likely to be hazardous to human beings. The system of testing and regulating new drugs, pesticides, and other products relies heavily on general predictions of hazard from animal studies. There is no question that dioxin has both acute and chronic toxicities in a wide range of animal species, and there is no reason to doubt that, under some conditions of exposure, it would also be toxic to human beings. The animal studies do not provide information about the level of risk to humans, or about whether people have actually been harmed by dioxin.

3. I do not know of a comprehensive list of diseases "associated with damage to or suppression of the human immune system." There are some conditions associated with severe immunosuppression, such as the opportunistic infections from which many AIDS patients suffer, and some malignancies seen in AIDS patients and in immunosuppressed transplant recipients. I am not aware of clinical conditions associated with less severe immune suppression, though this is not an area in which I consider myself an expert.

4. **1983 VA Agent Orange registry:** Veterans who are given the VA's Agent Orange physical examination make up the entries in the registry. Many of these veterans come to the VA because they have specific health problems that they feel may be related to Agent Orange. The VA has stated many times, and others have concurred, that the registry was not designed as a research tool. To my knowledge, there is no valid approach to analysing the frequency of diseases recorded in the registry to determine whether conditions are occurring excessively.

1983 Massachusetts study: I believe Mr. Kerry is referring to a study entitled, "Mortality Among Vietnam Veterans in Massachusetts, 1972-1983," dated January 25, 1985. As far as I know, this study was not published, and I will refer to the typescript version. The study uses a proportionate mortality approach, similar to the recent VA mortality study, but includes many fewer deaths. It compared the relative proportions of deaths among Vietnam veterans with those of non-Vietnam veterans and of the general male population (of Vietnam-era age) of Massachusetts. All cause-of-death information came from death certificates, with no additional confirmation from medical records. Veterans were identified by a "bonus list," which distinguishes Vietnam veterans from non-Vietnam veterans by the amount of bonus money they received. There is no information whatsoever in the study about exposure to Agent Orange, and the authors do not so attribute any of their findings.

Major findings included: elevated proportion of deaths due to motor vehicle accidents, suicides, and kidney cancer among Vietnam veterans compared with non-veterans, but not when compared with non-Vietnam veterans. Deaths due to stroke and connective tissue cancer (including soft-tissue sarcomas) were elevated among Vietnam veterans compared with both comparison groups. The connective tissue and kidney cancers were each based on nine deaths among the Vietnam veterans. Significantly fewer deaths than expected from circulatory system causes (other than stroke) were noted among Vietnam veterans compared with non-Vietnam veterans; and significantly fewer deaths from homicide among Vietnam veterans compared with the Massachusetts white male population.

1984 Ranch Hand Study: A significant excess of skin cancers was found in this study. I can find nothing in either the 1984 Air Force report or the 1988 Albanese discussion of these same data to suggest that there are any other significant cancer findings.

1985 Wisconsin Study: The final report of the Wisconsin study came out in 1986. According to that report, there was an excess of soft-tissue sarcomas when all Vietnam-era veterans were compared with all non-veterans. There was no difference when veterans with Vietnam service were compared with era veterans who had not served in Vietnam. The study had no index of Agent Orange exposure.

1986 West Virginia Study: Mr. Kerry cites excesses of non-Hodgkins lymphoma, and cancers of the testes, larynx, and respiratory system among Vietnam veterans. According to the report of that study that I have, the cancer findings are somewhat different. Higher than expected proportions of deaths from soft-tissue sarcoma, Hodgkins disease, and testicular cancer were found among Vietnam veterans when compared with non-Vietnam veterans. These were all based on very small numbers.

Preliminary VES results: Mr. Kerry may be referring to the mortality report from the VES, which was published in the Journal of the American Medical Association in February 1987, and is the only VES report that I know of released in 1987. Death rates from cancers of all types were nearly identical in Vietnam veterans and non-Vietnam veterans. There were only 14 cancer deaths among Vietnam veterans and 11 among non-Vietnam veterans, with no overall difference detectable, and no significant differences for any individual cancer type.

VA Mortality Study: OTA's interpretation of this study is reviewed in the testimony prepared for the June 8, 1988, hearing on veterans' health of the House of Representatives Committee on Veterans' Affairs, a copy of which is enclosed. I refer you to that document.

March 1988 Ranch Hand report: I assume this is the discussion of the 1984 Ranch Hand data by Dr. Albanese. OTA reviewed this document at the request of the House and Senate Veterans' Affairs Committees in a May 1988 Staff Paper (copy enclosed), and I refer you to that document.

Vietnam Experience Study: I generally agree with Mr. Kerry's characterization of the results of this study, except for his interpretation of the data on birth defects. The more reliable analysis was that using birth certificates and hospital records, which showed no excess. None of the findings could be linked to Agent Orange, as the study was examining possible effects of the total Vietnam experience, and no Agent Orange exposure measures were used.

1986 Kansas Study: This study is discussed in my testimony for the House of Representatives June 8 hearing, referred to above.

I refer you to my testimony also for an overview of the data linking Agent Orange to health effects in Vietnam veterans.

5.A. I am generally aware of studies in experimental animals that show a suppressive effect of dioxin on the immune system. It is logical to assume that the human immune system, given high exposures, might also be susceptible to adverse effects. What is not known, and seems to me important, is whether any effects, even if measurable in the laboratory, will actually lead to clinical disease of any kind, or otherwise impair the lives of those affected. Other than conditions associated with severe immune deficiencies, such as those associated with AIDS, we don't have a list of candidate diseases, other than, perhaps, a general increased susceptibility to infection. Although I do not claim to be fully conversant with current immunologic literature, I am aware of no studies showing clinical immunologic effects stemming from dioxin exposure, but the possibility of such effects remains plausible.

B. OTA's comments on the Air Force study are summarized in the House of Representatives June 8 testimony referred to above.

C. OTA's interpretation of the NCI Kansas study is summarized in the House of Representatives June 8 testimony referred to above. Regarding the possible conclusions Senator Daschle lists, the first two seem the more logical choices: either the excess of non-Hodgkin's lymphoma is unrelated to 2,4-D, or is the cause of it. He fails to mention the possibility of some interaction of 2,4-D with other agricultural chemicals commonly used by the subjects of the study. While it is true that forms of dioxin--4 different congeners, to be exact--have been detected in 2,4-D, these do not include

2,3,7,8-TCDD. None of the four is among the congeners with higher toxicity. If the culprit is 2,4-D, there is no reason to look beyond the compound itself.

D. The VA mortality study is discussed in the direct testimony presented at the May 12 hearing, as well as in the testimony before the House of Representatives, referred to above.

E. Adjusted analyses are certainly important, providing there is an a priori rationale for the adjustment, and that data on the distribution of the relevant risk factors are available. The 1987 Ranch Hand report provides both unadjusted and adjusted analyses in cases where those conditions are met. They also provide some subgroup analyses, to which Mr. Daschle refers.

F. Senator Daschle is correct that we would be more sure of the generalizability of the data if the birth records for children of all the study participants had been searched. CDC made a judgment that studying the records of the approximately 1,900 children born to a sample of Vietnam veterans and the 1,700 born to a sample of non-Vietnam veterans was large enough to draw generalizable conclusions. The sample would not be considered "small" by comparative standards, but one can always argue that it might have been larger. Although it was not a random sample from the entire study population, I cannot detect a potential bias in the way the samples were drawn, which, it seems to me, is the important point. I have seen no suggestion that the samples were biased in such a way as to influence the outcome one way or the other. I do believe that the data from birth and hospital records are more objective than what is reported by parents, and provide the better comparison. I have no reason to think that the comparison of recorded birth defects is biased in any direction. It is certainly true that learning disabilities or other problems that develop after birth would not be detected in a records-based study of birth outcomes. The Vietnam Experience Study could not detect such effects. However, that does not invalidate the finding that, at birth, there appeared to be no differences in outcomes.

G. I have read Dr. Kahn and colleagues' excellent article about the New Jersey Agent Orange study. I do not find the grounds in that article or elsewhere to invalidate the findings of CDC's "validation study." Their study seems to support CDC's findings. Even the one infantryman that New Jersey assessed by their own methods to have been heavily exposed had current levels of blood dioxin within the general background range.

H. I am not in a position to know about the protocol violations or breakdowns in peer review procedures referred to by Senator Daschle in his testimony. While we have reviewed and considered Ranch Hand Study reports, OTA does not have a formal role in that study.

JUNE 1988

TESTIMONY OF HELLEN GELBAND, SENIOR ANALYST
OFFICE OF TECHNOLOGY ASSESSMENT
U.S. CONGRESS
BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

CURRENT KNOWLEDGE OF VIETNAM VETERANS' HEALTH AND EXPOSURE TO AGENT ORANGE

June 8, 1988

I am Hellen Gelband, a Senior Analyst at the Office of Technology Assessment (OTA) with primary responsibility for issues related to veterans' health. I am pleased to appear before this subcommittee to offer OTA's perspective on the epidemiologic findings concerning the health of Vietnam veterans, and on the current state of knowledge about exposure to Agent Orange in Vietnam.

Since passage of Public Law 96-151 in 1979, OTA has been one of several groups reviewing and attempting to interpret the evidence concerning potential adverse health effects of Vietnam service, and particularly, of exposure to Agent Orange. We have carried out the statutory responsibilities mandated in PL 96-151 and subsequent laws--reviewing protocols for mandated studies and monitoring their conduct. Over the past eight years we have also, at the request of this committee and of the Senate Veterans' Affairs Committee, formally reviewed the major studies of Vietnam veterans and of chemical and herbicide exposures that have bearing on the Agent Orange issue.

Findings from several important studies of Vietnam veterans' health have become available in the last year. The recently published Vietnam Experience Study, undertaken by the Centers for Disease Control (CDC) under the mandates of PL 96-151 and PL 97-72, is the most prominent. In October 1987, the Air Force reported results of the second round of interviews and physical examinations of the Ranch Hand study (formally, the Air Force Health Study). In 1987, the Veterans Administration (VA) completed a proportionate mortality study of about

50,000 veterans who had died since the end of the Vietnam War. Before I summarize the findings from these and some other studies of herbicide exposure, I would like to recount briefly the research to date on what is known of exposures of Vietnam veterans to Agent Orange.

Exposure to Dioxin-Containing Herbicides in Vietnam

PL 96-151 mandated a study of the long-term health effects of Agent Orange exposure among ground troops in Vietnam. At the time the law was written, the belief was widespread that, given the millions of gallons of Agent Orange sprayed and smaller amounts of other dioxin-containing herbicides, just being in ground combat in Vietnam must have guaranteed significant exposure. When CDC assumed responsibility for the study in 1983, a major concern in the design was whether it would be possible to identify enough unexposed ground troops with whom the exposed could be compared.

In the painstaking process of examining spray records and troop movements, carried out by the U.S. Army and Joint Services Environmental Support Group (ESG), a more complex picture began to emerge. First, the uncertainties inherent in developing an exposure index from military records became clear: while it was possible to define approximately at least one daily position for most military units in Vietnam, some or all of the troops might actually have been many kilometers from that position at various times during the day. It would never be possible to determine the locations of individual men in the field. The records do not contain that level of detail, and the best research cannot compensate for that lack.

If it had been the case that the general areas occupied by troops were constantly sprayed with Agent Orange by Operation Ranch Hand while troops were present, the inability to locate ground troops precisely would be of lesser consequence. But, in fact, spraying was not constant, as the defoliation caused by a single spray or series of sprays lasted many months, and it was rare for troops to be sprayed directly. While the heavily-sprayed areas may have had many separate applications, many areas were sprayed far less frequently. It appears, therefore, that direct exposure during or shortly after Ranch Hand spraying would have been relatively rare among ground troops. Whether significant exposure could occur by being in an area days, weeks, or months after spraying was unknown, and still is, to some extent. However, based on the amount of spray that was likely to have reached the ground, and on what is known of the environmental fate of the herbicide components, including dioxin, it appeared unlikely that significant exposure would have occurred in that way. The remaining uncertainty could not be resolved through more records research, however.

With exposures to Ranch Hand spraying lower than expected, it became important to seek information about non-Ranch Hand uses of Agent Orange to which ground troops might have been exposed. It is known that herbicides were sprayed around base perimeters by Army helicopters, by truck-mounted sprayers, and by men with backpack sprayers, and riverbanks were sprayed from boats. Though these activities accounted for only a small percentage of the total Agent Orange used, it was possible that they resulted in more direct exposures to ground troops than did Ranch Hand sprays. The ESG documented large numbers of these other sprays, but many were not recorded anywhere, and individual sprayers were not always identified in company records.

Many uncertainties remained, but a picture began to come into focus. The best evidence suggested not ubiquitous exposure, but possibly a relatively small number of men with significant exposure. In addition to the clearly exposed Ranch Hands and chemical corpsmen, there were undoubtedly others who had sprayed base perimeters or who had directly handled herbicides in other ways. Some bystanders were probably exposed directly during these operations. Even knowing that contact with Agent Orange occurred, however, it was impossible to define what might constitute a "significant" exposure.

CDC was then confronted with the apparent infeasibility of using military records alone to identify a large group of ground troops with unequivocal Agent Orange exposure, as well as with doubt that a large percentage of ground troops had had significant exposure. To verify the suspected lack of correlation of military records-based exposure estimates with actual exposures, and to learn about relative levels of exposure, CDC undertook its "Comparison of Serum Levels of 2,3,7,8-TCDD With Indirect Estimates of Agent Orange Exposure in Vietnam Veterans," referred to as the "validation study." This study capitalized on new technology to measure dioxin levels in blood serum, which appears to be a reliable indicator of current dioxin body burden, and which, at least at the group level, correlates with heavy past exposures, even many years earlier.

The validation study showed no significant differences between Vietnam veterans and non-Vietnam veterans in average dioxin levels and in the distribution of levels. In both groups, the levels are generally within the "background" range expected in the U.S. population. The rankings resulting from five different methods of classifying exposure used within the Vietnam veteran group were not mirrored in gradations of dioxin levels: for each method, men classified as likely to have had higher exposures did not have higher dioxin levels. Two out of 573 Vietnam veterans with completed tests had dioxin levels of 25 and 45 parts per trillion (ppt), somewhat above the level of 20 ppt that CDC has estimated as the upper limit of "background." Neither of these individuals had a "high" exposure ranking. None of the 88 tested non-Vietnam veterans had a level above 20 ppt, the highest being measured at 15 ppt.

In contrast to the ground troops tested, a group of 30 Ranch Handers with known direct exposure to Agent Orange during the same time period in which the ground troops served, had much higher levels. About half of them had levels greater than 100 ppt, and several were above 300 ppt. The recent New Jersey Agent Orange Commission study also found persistent high levels in men who had handled herbicides.

Information about the biological half-life of dioxin, a measure of persistence in the body, was gathered in conjunction with the validation study. In the half-life study, the 1982 dioxin blood levels of a group of Ranch Handers were compared with their levels in 1987. The rate of decline of dioxin blood levels was calculated based on the difference between the two samples. This study was possible because the Ranch Hand investigators had stored small samples of blood drawn during the first Ranch Hand Study physical examination in 1982 and were able to call upon selected participants to have blood drawn again in 1987. The men were selected by the Ranch Hand investigators as having had probable "high" Agent Orange exposures, based on their experiences in Vietnam. The study was necessarily limited to Ranch Hands with relatively high exposures. Because only small amounts of blood had been stored in 1982, and because the analytic technology for measuring dioxin levels has lower limits, only men with levels of at least 10 ppt in 1982 were included. There is no information, therefore, about the rate of change in dioxin levels among men whose previous levels were already in the "low background" range.

The median half-life of dioxin determined from the paired Ranch Hand blood samples was 7.1 years. (The half-life calculation was based on the assumption that dioxin clearance from the body follows "first order kinetics," meaning that, for a given period of time, a constant fraction of the dioxin body burden is eliminated. That assumption is supported by data from other sources, mainly animal studies, but no corroboration from the Ranch Hand sample itself of the clearance kinetics during an early period after exposure.) In none of the men was there a high level in the 1982 sample and a very low level in the 1987 sample. Therefore, there is no reason to believe that the ground troops, whose dioxin levels are now quite low, would have had high dioxin body burdens while in Vietnam or more recently.

This is the evidence that exists to date. At least some of the men who handled herbicides regularly were exposed to a degree that they retain elevated levels of dioxin in their bodies. Based on current evidence, it appears that few ground troops have elevated levels of dioxin in their bodies. The ground troops tested may not be representative of all ground troops, but CDC, in its validation study, did attempt to identify men who spent much of their tour of duty in heavily-sprayed areas, who, of the ground troops, should have had the greatest potential for exposure. The general dioxin profile of this group was identical to that of men who had not been in Vietnam. There is, of course, no guarantee that exposure would have to have been so high as to result in a currently elevated body burden for some long-term health effect to result. The lack of elevated levels does diminish the expectation of such a finding, however, and forces greater reliance on the epidemiologic data for inferences about health effects.

This body of information on exposure of ground troops to Agent Orange--the low levels suspected from records and confirmed in the validation study, and the inability to distinguish exposed from non-exposed, caused CDC to recommend cancellation of their proposed Agent Orange study. The Agent Orange Working Group and OTA agreed that the study was not feasible.

Recent Studies of Vietnam Veterans' Health

No simple set of answers will ever be found to questions about the health of Vietnam veterans. No single study will be the key to understanding. Vietnam veterans, while sharing a collective experience, are diverse, with varying pre- and post-Vietnam experiences. Even while in Vietnam, they served in different areas, with differing responsibilities and activities. The studies that have been completed and those under way come at the questions from different angles, from broad sweeps--like the Vietnam Experience Study--to disease-specific targets--like the Selected Cancers Study. Information from all the studies, taken together, should tell us if there are widespread health problems in the Vietnam veteran population, and if specific conditions, which are suspected to be related to aspects of Vietnam service, are occurring more frequently among the veterans. What may be missed are Vietnam-related conditions occurring rarely in the entire veteran population, or conditions occurring in particular subgroups of veterans who had some common, but not widespread, experience. Here are the major findings of studies that have been completed as of mid-1988.

JUNE 1988

Vietnam Experience Study

CDC conducted the Vietnam Experience Study (VES) under the mandates of Public Laws 95-151 and 97-72. When CDC assumed responsibility from the VA for these mandates in 1983, this study was planned as one of three, the other two being the ongoing Selected Cancers Study and the Agent Orange Study (which has been canceled because of infeasibility). The VES was designed to find out if there were widespread health problems of any type affecting the general population of Vietnam veterans, by comparing them with veterans who were similar in other ways, but who did not serve in Southeast Asia. In all, more than 15,000 veterans were interviewed, and more than 4,000 underwent intensive physical and psychological examinations.

Of the thousands of questions and measurements taken, a few key findings of significance emerged. The Vietnam veterans show persistent psychological effects from their wartime experience, notably continued symptoms of post-traumatic stress disorder (PTSD) even 20 years after service. Other psychological and emotional problems are also affecting greater numbers of Vietnam veterans than their non-Vietnam veteran counterparts.

Two physical findings are of concern. First, more Vietnam veterans have experienced high-frequency hearing losses than have non-Vietnam veterans, and this is correlated with their combat experience. Second, and more puzzling, more Vietnam veterans have had difficulty conceiving children and more also have low sperm counts compared with the non-Vietnam veteran comparisons.

An additional finding, one that appears to apply broadly to Vietnam veterans, is heightened concern over their own and their children's health. In interview, many more Vietnam veterans than non-Vietnam veterans reported that they themselves and their children had health problems. When the veterans were examined, however, there were few differences other than those that I have noted. Similarly, when asked about their children, Vietnam veteran fathers reported more problems than the comparison fathers. When actual birth and hospital records were examined, however, there were no differences. Vietnam veterans seem to be more aware of the kinds of health events that may not even be noted or recalled by those without Vietnam in their past.

The "Ranch Hand Study"

The Ranch Hand Study (formally, the Air Force Health Study) was begun by the Air Force in 1978 to determine whether those exposed to Agent Orange in Operation Ranch Hand, the main herbicide-spraying force in Vietnam, were suffering adverse health effects as a consequence. The Ranch Hands were compared with a group of Air Force veterans who also served in Vietnam, but who did not spray herbicides. Differences found between the two groups might be attributable to Agent Orange, to which the Ranch Hands had relatively heavy "occupational" exposure (which was discussed earlier in regard to exposure information). In October 1987, a report of the second round of in-depth interviews and intensive examinations of the Ranch Hand participants, conducted in 1985, was released. The results included the 1985 findings and comparison with results of the first interviews and examinations, conducted in 1982.

Few overall differences overall were found between Ranch Hands and comparisons. One, however, is an excess of skin cancers among Ranch Hands, taking into account the follow-up period from discharge through 1985. The excess results from tumors arising through 1982, with no differences noted in the interval between the first and second examinations. This finding is not entirely explained by the major variables usually associated with these cancers (skin tone and exposure to the sun).

The other area still under investigation is the incidence of adverse birth outcomes. In 1982, the men were asked about the children that they had fathered (and other pregnancies not resulting in live children). Significantly more Ranch Hands reported birth defects and deaths shortly after birth than did the comparisons. A decision was taken by the Air Force investigators to seek full documentation of the approximately 5,000 births to men in the study.

Until the collection and analysis of that information is complete, sometime in late 1989, it is not possible to draw conclusions about possible adverse effects on the reproductive capacity of the Ranch Hands. CDC'S finding in the VES, of higher problem-reporting rates, unsubstantiated by medical records, among Vietnam veteran fathers, should add to the caution with which the events reported by Ranch Hands are interpreted.

The Ranch Hand Study will continue with periodic interviews and examinations for the next 20 years. A new dimension to the exposure assessment is about to be added, with determination of blood dioxin levels in all participants. Samples for this purpose were collected during the 1985 examinations and have been stored, and the Air Force is now making arrangements with CDC to have the analyses completed. Results of analyses using these data will be of potentially great importance to the understanding of Agent Orange exposure and its possible effects on Vietnam veterans, and beyond that, to the larger field of dioxin-related research. It will be the first study of a relatively large group of exposed individuals in whom actual body burden of dioxin will be used as a measure of exposure. By reducing misclassification of exposed and unexposed, the study should have greater power to detect Agent Orange effects, if they exist.

VA Proportionate Mortality Study

In this study, the VA examined the causes of death for about 50,000 Army and Marine veterans, about half of whom served in Vietnam and half of whom served elsewhere during the Vietnam era, who died since their discharge from the service. The most striking findings, consistent with findings in several state mortality studies of veterans, concerned excesses of deaths from external causes--motor vehicle accidents, accidental poisonings (including drug overdoses), and other accidents and injuries. The excesses in each category were a relatively small percentage of the total deaths in those categories, but because those categories contain a large percentage of the deaths occurring to young and early-middle aged men, they represent substantial numbers. Other findings include significantly fewer deaths due to suicide than expected, and, among Marines, a greater number than expected due to homicide.

Two other statistically significant findings from this study have occasioned great concern: larger than expected numbers of deaths from lung cancer and from non-Hodgkins lymphoma (NHL) among Marine Vietnam veterans. In Army veterans, a slight deficit of NHL, though not statistically significant, appeared. No information on exposures of any kind, either from military or civilian life, is available to guide interpretation of this study. There is no a priori reason to believe that the excess is due to Agent Orange, particularly in light of the results for the Army. The Marine finding is based on a total of 35 deaths from NHL among Marines, which represents about twice the proportion of deaths expected from the Vietnam-era Marines. This is not a large number, nor is the result so extreme as to be alarming, particularly as a result of a proportionate mortality study design, which has inherent limitations and can produce spurious results. However, as stated in OTA Director Gibbons' letter of October 23, 1987, to Chairmen Cranston and Montgomery regarding this study, we believe that this finding "should be taken seriously and that follow-up work be done to investigate possible explanations."

We understand that VA has been obtaining information to carry out some additional analyses suggested by OTA and other review groups. In our view, however, the most important piece of information will come from the NHL portion of CDC's Selected Cancers Study. Information on a wide range of risk factors for NHL will be generated by this study, and it may help put together the fragmentary picture that now exists regarding NHL, occupational exposures to herbicides and other chemicals, and the risks for veterans. While that study will undoubtedly leave many questions unanswered, the information it does produce will be of tremendous value in interpreting what now exists.

The lung cancer finding should be of lesser concern. The finding is based on a total 130 lung cancer deaths, with the excess being 40 to 50. The Army Vietnam veterans showed no excess. Cigarette smoking is the most obvious potential cause of the excess lung cancer deaths.

It would be logical to examine this possibility before searching for less plausible connections. OTA Director Gibbons commented on this in his October 23, 1987, letters to Chairmen Cranston and Montgomery stating that "it is essential that smoking histories be obtained for these cases, and even more importantly, that information about smoking rates of Marines and other servicemen who did and did not serve in Vietnam be gathered." Differences in smoking prevalence between groups are not uncommon. The Ranch Hand study, for example, reports a significantly higher smoking rate in the Ranch Handers than in the comparisons, and the men in both of those groups served in Vietnam.

Summary

A great deal of progress has been made over the past few years in redefining and clarifying the question of exposure to Agent Orange in Vietnam, and in studying the health of Vietnam veterans. Current efforts, including the continuing Ranch Hand Air Force Health Study and its upcoming serum dioxin measurements, and studies reported to be under way by the New Jersey Agent Orange Commission, will help to further define the bounds of exposure.

Thus far, a relatively small number of psychological and physical effects of Vietnam service have been observed among veterans. At present, none of these appears to be related to Agent Orange. However, the possible effects of Vietnam service and Agent Orange continue to be investigated directly in the nearly complete National Vietnam Veterans Readjustment Study (looking at PTSD), CDC's ongoing Selected Cancers Study, in the continuation of the Ranch Hand Study, and in efforts by state Agent Orange agencies, in particular, New Jersey. In addition, a mandated study of women Vietnam veterans is in the planning stages.

OTA Review of:

"United States Air Force Personnel and Exposure to Herbicide Orange"
Richard A. Albanese, M.D., February 1988 (USAFSAM-TR-88-3)

Staff Paper
Prepared by Hellen Gelband

Special Projects Office of the Health Program

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MAY 1988

OTA Review of:

"United States Air Force Personnel and Exposure to Herbicide Orange"
Richard A. Albanese, M.D., February 1988 (USAFSAM-TR-88-3)

This review was prepared in response to a March 30, 1988, letter from the Chairmen and Ranking Minority Members of the House and Senate Veterans' Affairs Committees, asking that OTA provide comments on the technical aspects of this report.

The reinterpretation of results of the first Air Force Health Study morbidity report (AFHS)[1], by Richard A. Albanese, M.D., does not diverge greatly from the original Air Force interpretation, and no new findings emerge from it. Albanese has not taken issue with the method of the analyses (except in the case of cancers, discussed below), nor with the analytic results. The main concern expressed by Albanese is that the 1984 findings not be taken as proof that Agent Orange has not affected or will not in the future affect the health of Ranch Hands. To support his concerns, he cites animal studies and other epidemiologic studies, and highlights selected AFHS findings in which significant differences between Ranch Hands and comparisons were found. Dr. Albanese also comments on the Agent Orange exposure estimates used. This reinterpretation does not have a particular study design, in the usual sense of the phrase, and it is not subject to a formal independent quantitative analysis.

The major areas in which Albanese noted evidence which he judged to support an effect of Agent Orange (in his summary table 19) are commented on below, and corresponding information in those subject areas from the second examination[2] is added. In general, from the first to the second morbidity reports, some shifts have occurred, with the Ranch Hands having slightly better test measurements than the comparisons in some cases, and slightly worse in others.

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[1] Lathrop, George D., Wolfe, William H., Albanese, Richard A., and Moynahan, Patricia M., Air Force Health Study (Project Ranch Hand II): An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides, Baseline Morbidity Results, 24 February 1984.

Exposure Index

Albanese states a major concern about the exposure index used in the study, commenting that misclassification may obscure Agent Orange dose-related relationships. This has also been a concern of the Ranch Hand researchers. If the Air Force implements its proposal to measure blood dioxin levels in the study population, this issue should be greatly clarified, though undoubtedly a certain amount of misclassification will still remain. Until these measurements are made, there is no way to estimate the effect of misclassification.

Neoplasia

Albanese reinterprets the data on cancer, asserting that, for all malignant cancers combined, the rate in the Ranch Hand group is about twice as high as the original control group, and that the difference is statistically significant. The main Air Force 1984 analysis split cancers into those of the skin and all others, categorized as systemic. They reported a significant excess of skin cancers (the vast majority in both groups being generally curable nonmelanomas) in the Ranch Hand group, but no difference in systemic cancers. Albanese criticizes this separate analysis as being based on a decision made after the data had been examined, rather than on a plan stated in the study design.

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[2] Lathrop, George D., Wolfe, William H., and co-authors, Air Force Health Study: An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides, First Followup Examination Results, October 1987.

Nonmelanomas are the commonest malignancies in relatively healthy, middle-aged men, and the total number of cancer cases in this study is dominated by them. While it is not wrong to look at total cancers, it is of greater epidemiologic interest, where numbers of cases are sufficiently large, to identify more specific types of cancer in which the groups differ, rather than to claim an excess in a broader category. Albanese himself did not hypothesize that one would expect an overall increase. Because the numbers of each specific type of systemic cancer are small in both groups, it is not possible to analyze each one separately, though that is theoretically desirable. Lumping all cancers together does give greater overall power to detect an excess in total cancers, but it produces cruder information than do site-specific analyses. In this case, stating that there appears to be an excess of skin cancers (specifically, nonmelanomas) is more informative and uses the data better than does a claim of excess total cancer.

The numbers Albanese chose to include in his analysis of neoplasia may be influenced by a bias that, as far as can be detected, is not mentioned by Albanese or by the 1984 report. Albanese bases his analyses on data from Ranch Hands and original comparisons who were both interviewed and examined (1045 Ranch Handers and 773 original comparisons). The 1984 report gives both these figures and those for the group that completed the interview only. For cancers, he reports the following numbers of confirmed (by medical or pathological records) cases:

TABLE 1

Group	Skin Cancer No. (%)	Systemic Cancer No. (%)	Total
Ranch Hand	35 (3.3)	13 (1.2)	1,045
Comparison	10 (1.3)	8 (1.0)	773

The corresponding numbers from all interviewed Ranch Hands and original comparisons are the following:

TABLE 2

Group	Skin Cancer No. (%)	Systemic Cancer No. (%)	Total
Ranch Hand	35 (3.0)	14* (1.1)	1,174
Comparison	15 (1.6)	10 (1.0)	956

*one of these men died between interview and examination

A comparison of the figures in these two tables suggests that a self-selection bias may have been operating, whereby Ranch Handers who had had cancer (and potentially other conditions) were more likely to complete the examination than were comparisons. This type of self-selection is not illogical, if Ranch Handers believe that Agent Orange may have been responsible for their cancers, and are more motivated to participate in a study that might shed light on that relationship.

Based on the figures in Table 1 above, Albanese reported a statistically significant relative risk of 1.97 for all cancers combined. The data in the second table above yield a relative risk of 1.6, which is not significant. A relative risk of 1.9 for skin cancer is still statistically significant. If there really is a self-selection bias operating here, however, it could extend back to those agreeing to the interview in the first instance. If it followed the pattern associated with agreeing to the examination, it might mean that the Ranch Hands with cancer would be more likely to participate than comparisons with cancer. The excess skin cancer finding should certainly not be ignored, but it should not be overinterpreted either, and these possible biases should be taken into account.

According to the 1987 report, incidence of skin and systemic cancers during the interval between the first and second morbidity surveys was not significantly different between Ranch

Hands and comparisons. Looking at the entire followup period (combining initial incidence with interval incidence), there was again no significant difference in an "unadjusted" analysis. However, when the analysis was adjusted for varying distributions of characteristics known to affect the incidence of the predominant form of skin cancer--skin color, reactivity to the sun, occupation, latitude of residence--there was a significant excess among the Ranch Hands (relative risk of 1.56) not explainable by other known factors.

Birth Defects

A significant excess of birth defects reported by Ranch Hand parents is given considerable attention by the 1984 report and by Albanese. The Air Force has not dismissed this finding and is in the final stages of obtaining birth records for all births to all study participants. The analysis based on actual records (rather than parents' reports) will allow complete exploration of this important area. Dr. Albanese's concern is well taken, and the action by the Air Force is a comprehensive one.

Psychological Assessment

Albanese bases his report of significant adverse psychological findings on responses to questionnaires showing the Ranch Hands to be less well on the following indices: fatigue, anger, mental erosion, anxiety, isolation, and depression. The depression finding was not corroborated by responses to a test administered during the physical examination. In one case, an index of denial, the comparisons were less well, but this is not reported by Albanese, which seems arbitrary. The 1987 data show fewer differences, and the differences are split more evenly with respect to which group has the more favorable measurement. On the one specific measure designed to detect possible organic causes for psychological effects, no differences between Ranch Hands and comparisons were found. There were also no significant differences in the frequency of actual psychologic pathology, i.e., in the number of diagnosed cases of mental disorder. A reanalysis of these data using the blood dioxin levels as surrogates for exposure may prove useful in determining whether such an effect exists.

Hepatic Examination

Differences between Ranch Hand and comparisons in certain laboratory measurements were noted by the 1984 report and by Albanese. Albanese also points to a highly significant difference in the number of liver disorders other than hepatitis, jaundice, or cirrhosis reported by participants and verified in their medical records. Of the 13 reported in Ranch Hands, 10 were of an unspecified nature, making this an uninterpretable finding.

At the second examination, some shifts had taken place, and the 1987 report states that, of the measures in which there were significant differences, about half tended to favor the Ranch Hands and half the comparisons.

Cardiovascular System

The significant finding in this area was poorer peripheral pulses among some Ranch Hands. This finding was no longer significant by 1987. The researchers suggest that, in part, the lack of a difference in the later examination may be due to the participants being asked not to smoke before the examination, because smoking directly affects the vascular system. This had not been the practice during the first examination.

Endocrinologic Effects

Differences between the two groups in several laboratory measures were noted by Albanese and the 1984 report. By the second examination, at least some of these differences had disappeared, and overall, the Ranch Hands and the comparisons differed on a number of measures, some in which the Ranch Hands fared better, and some in which the comparisons fared better.

Conclusion

The report by Dr. Albanese does not call into question any of the findings reported directly by the Air Force study team in their original reports. Albanese does draw attention to the fact that the study results cannot be taken to mean that Agent Orange is not harmful, or that the Ranch Hands are entirely free of any effects. The study is limited by its size and by the relatively young age of the participants. Other than continuing to study this group, as is planned, and to use new technology to determine dioxin body burdens, the reinterpretation does not suggest interventions of any kind or new directions for AFHS.

PVA

PARALYZED VETERANS
OF AMERICA
Chartered by the Congress
of the United States

June 15, 1988

The Honorable Alan Cranston
Chairman
Committee on Veterans' Affairs
SR-414 Russell Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman,

I am pleased to respond to your follow-up questions regarding the Agent Orange hearing held May 12, 1988.

1. Question: Please provide your organization's assessment of the Centers for Disease Control's "Vietnam Experience Study" results published in the May 13 issue of The Journal of the American Medical Association.

Answer: Last month, the Centers for Disease Control released the findings of the "Vietnam Experience Study (VES)." The study was a multidimensional assessment of the health of Vietnam veterans using a random sample of enlisted men who entered the U.S. Army from 1965 through 1971 - 7,924 Vietnam and 7,364 non-Vietnam veterans participated in a telephone interview; a random subsample of 2,490 Vietnam and 1,972 non-Vietnam veterans also underwent a comprehensive psychological and medical examination. The findings of the study revealed:

° Certain psychological problems were significantly more prevalent among Vietnam veterans than among non-Vietnam veterans. These included depression (4.5% of Vietnam veterans vs. 2.3% of non-Vietnam veterans), anxiety (4.9% vs. 3.2%); and alcohol abuse or dependence (13.7% vs. 9.2%); about 15% of Vietnam veterans experienced combat-related post traumatic stress disorder at some time after military service, and 2.2 had the disorder during the month before the examination. Elevation of PTSD in Vietnam veterans showed a strong association with higher levels of combat experiences.

° Still, 15 to 20 years after Army service, Vietnam veterans seemed to be functioning socially and economically in a manner similar to Army veterans who did not serve in Vietnam.

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° Vietnam veterans reported current and past health problems more frequently than did non-Vietnam veterans. However, the results of the medical examination showed few current objective differences in physical health between the two groups.

° Perceived exposure to herbicides (a perception that in itself may lead to additional stress) is associated with self-reported adverse health conditions, but is not associated with objective measures of exposure. The higher prevalence of psychological problems among Vietnam veterans does not seem to be related to their being in worse physical health.

° The review of general health experience between the two groups showed no elevation among the Vietnam veterans cohort of disabilities which have been suggested as being related to prior exposure to herbicides or dioxin.

° Vietnam veterans, particularly those who served in tactical military occupational specialties, have higher levels of hearing loss than non-Vietnam veterans.

° Among a subsample of the participants who had semen samples evaluated, Vietnam veterans demonstrated lower sperm counts and a significant decrease in the average proportion of "normal" sperm cells than non-Vietnam veterans. Researchers were unable to determine the reasons for differences in sperm characteristics. However, further analysis showed no difference in fertility histories or birth defects among the two groups.

In summary, PVA believes the results of this study should be encouraging for the vast majority of Vietnam veterans. The study revealed no insidious undercurrent of disabilities undermining the physical health and well-being of the Vietnam veteran population. In fact, the study showed clearly the opposite; that the vast majority of Vietnam veterans have readjusted from military service socially, economically and from a standpoint of general physical health at a level equivalent to their non-Vietnam veteran peers.

We are concerned, however, that the study has once again shown that there is still a lingering higher percentage of psychological disabilities among those veterans who served in Vietnam. As is expected, these disabilities, including post traumatic stress disorder, manifest themselves at higher intensity levels with higher degrees of combat experience.

In this connection, one of the most disturbing revelations of the VES study was the demonstrated incidence among Vietnam veterans of a potential anxiety reaction over Agent Orange itself. For many Vietnam veterans the fear of Agent Orange can be worse than Agent Orange itself. Hopefully, this study, with its positive implications for the health and well-being of the vast majority of Vietnam veterans, can help allay those fears.

2. Question: Does your organization have any concerns regarding the operation of the VA's Agent Orange Registry? Should the registry be updated for current addresses, and if so, how could that feasibly be done?

Answer: PVA recognizes the purpose of the Agent Orange Registry as a means by which the Agency can maintain an accounting of all individuals who claim to have been exposed to Agent Orange. We do not see a need to update the registry for current addresses beyond using the mechanisms already in place for VA address changes. By utilizing the existing Target System and VAMC records, we believe any potential need for current addresses will be satisfied. Regarding the dissemination of information about Agent Orange, the combined efforts of the VA, the Veterans' Service Organizations, and the media should be sufficient to inform most interested parties.

3. Question: Is your organization satisfied with both the design of the VA Agent Orange medical examinations and the way they are conducted?

Answer: It is the opinion of PVA service representatives that the Agent Orange medical examination is designed appropriately and, in general, conducted adequately. There is general agreement that the exams are thorough and that necessary follow-up exams and tests are scheduled without difficulty. Although we have no way of knowing for certain, there exists an undercurrent of belief that the VA "over reports" Agent Orange exams by including in the official count those individuals who are being examined for other reasons and happen to mention Agent Orange during the course of the exam. The only other negative comments we received indicated that although an individual is appropriately informed about any adverse health condition, there is no attempt made to advise the veteran if the Agent Orange exam showed nothing to be wrong.

4. Question: Without regard to the outcome of presumptive compensation legislation, does your organization see value in continuing ongoing Agent Orange research?

Answer: The main purpose of spending millions of dollars in an investigatory effort to study the health status of the Vietnam veteran population and any possible adverse effect of Agent Orange exposure has been to determine if compensation is warranted. Without regard to the outcome of presumptive compensation legislation, PVA still supports ongoing Agent Orange research. We believe continued research is critical to either allay or confirm the deep concerns thousands of Vietnam veterans have developed over the potential effects of dioxin. The severe anxiety manifested by many veterans, as shown in the CDC study, can be worse than Agent Orange itself.

Sincerely,

John C. Bollinger
Associate Legislative Director

JCB:das

WRITTEN QUESTIONS FROM CHAIRMAN CRANSTON TO

GENERAL SLOAN AND THE RESPONSES

1. Air Force comments on the verification of self-reported birth defects:

In Dr. Wolfe's 25 August 1987 letter to Senator Daschle he states: "Verification of all reported birth defects in the children fathered by the participants in our study was conducted using medical records and birth certificates in 1984. Sixty-one percent of the defects reported by the Ranch Handers and their wives and 63% of those reported by the comparisons were verified as codable defects." At that time, none of the "normal" children's records had been reviewed. The current team of Air Force investigators and the Advisory Committee felt that the analysis was premature and unsuitable for valid interpretation without full verification of all births.

The preliminary analyses of birth defects did not account for clustering of birth defects within families and grouped the reported defects by body organ system rather than by whether or not they could have been caused by direct toxic effects on the developing fetus or by altered or mutated chromosomes of the parents (biological mechanisms).

The investigators felt that it was imperative to review records from all children fathered by study participants. This process of record retrieval and review for more than 6,000 children is expected to be completed in November 1989, with a published report anticipated during the summer of 1989.

Within the past year, Air Force statisticians have developed new statistical approaches to these data and have obtained new statistical techniques from the Centers for Disease Control (CDC) that will accommodate family genetic history. They have also worked with CDC geneticists and epidemiologists to devise analyses that will account for biological mechanisms. There has never been any attempt to mislead, delay or cloud the resolution of the birth defect issue.

2. The Air Force's "1988 interim report on the Ranch Hand Study."

It is correct that this 1988 report and the 1984 report did reach essentially the same conclusions. From the 1984 report: "This baseline report concludes that there is insufficient evidence to support a cause-and-effect relationship between herbicide exposure and adverse health in the Ranch Hand group at this time. The study has disclosed numerous medical findings, mostly of a minor or undetermined nature, that require detailed follow-up." From the 1988 report: "In six of 11 clinical areas, statistically significant group differences occurred, and in five of these six instances, the group differences were in the direction of expected dioxin effects. Dioxin cannot be confidently identified as the causative agent of these findings at this time. ... However, dioxin is not exonerated as a causative agent. ..." Therefore, our study is a planned 20 year research effort.

Technical Report 88-3 contrasted the 1984 data with a literature search concerning dioxin. The clinical areas Dr. Albanese highlights were, in fact, clearly mentioned in the 1984 report as exhibiting group differences. These areas, in turn, were subjected to more intensive follow-up evaluation during subsequent phases of the ongoing study.

The observation of an increase in systemic cancer among the subgroup of enlisted fliers in the Ranch Hand group is of great interest, but its relevance is unknown at this time. The finding is based on only five cases of cancer in the Ranch Hand enlisted fliers. The occurrence of only two cases in the comparisons would make the finding no longer statistically significant. It is interesting to note that in an equivalent group of men from the general population, one would expect to find two cases. This may indicate that the finding could represent a decrease in the comparisons rather than an increase in the Ranch Hands. We anticipate that the ground enlisted personnel were generally more exposed to dioxin than were the enlisted fliers, and that group did not exhibit any differences in cancer.

The Air Force team of investigators is fully committed to pursue these observations in subsequent mortality and morbidity reports, using improved measures of exposure derived from the serum dioxin assay.

3. The Air Force scientists' confirmation in their testimony of four conclusions relating to the Air Force Health Study that Senator Daschle sets forth:

Birth Defects

The investigators agree that the increase in reported birth defects in the children of Ranch Hand personnel is an important finding, but the relevance of this observation must await the results of the reanalysis using fully verified data. The effect of differential patterns of reporting, both over-reporting and under-reporting can have drastic impact on the results of the analysis. In the Vietnam Experience Study, the CDC found that Vietnam veterans reported a statistically significant number of birth defects as compared to the control group. However, when these reports were verified the difference was no longer statistically signficant.

The Exposure Index

The investigators agree that the exposure index used in the 1984 and 1987 analyses was subject to limitations. It is an exposure estimate based upon the best calculation of the effective number of gallons of herbicide to which the airmen were exposed. It was based on an estimate of gallons of herbicide sprayed each month (1962-1971), the levels of dioxin contamination and the number of men assigned each month. Individual exposure estimates could not be made. While this method was limited it was state-of-the-art at the time. These limitations were clearly discussed in each of the published reports, and concern for these limitations led to an intensive program to use the serum dioxin determination as an improved measure of exposure.

The testing of an initial group of 200 study participants did indeed confirm that some of the Ranch Hands were heavily exposed to dioxin. The mean level of dioxin in the serum of the 147 Ranch Hand participants was 10 times higher than that of the 49 comparisons.

The 1988 Interim Report

The USAFSAM Technical Report 88-3, authored by Dr. Richard Albanese and released in February 1988, is technically correct. Both Colonel Wolfe and Dr. Michalek did work with Dr. Albanese in the preparation of the report. However, they were unable to reconcile differences with Dr. Albanese concerning the tone and writing style of the report and withdrew their names as co-authors.

4. The exposure index used in the Ranch Hand Study:

Our initial work developed an estimated exposure index that reflected the best calculation of the number of gallons of herbicide to which the Ranch Hand members were exposed. It was based on the estimate of the number of gallons of herbicide sprayed per month (1962-1971), the levels of dioxin contamination and the number of men assigned each month. Individual exposure measures could not be made. Calculations of indices of this type is a standard approach in epidemiologic studies of occupational groups. The index was based on assumptions of individual work habits since industrial hygiene data were not collected or maintained on the Ranch Hand operation. A separate index was constructed for each occupational category. It was recognized that this index was not precise, but it was the state-of-the-art in epidemiologic methods. The limitations of the index, the assumptions implicit in its construction and the preliminary nature of the results were clearly stated by the authors in the previous Air Force reports.

5. The use of blood analyses to determine dioxin levels in the Ranch Hand Study participants:

The ability to improve the estimated exposure index with the serum dioxin test is a major opportunity in the scientific evaluation of the Agent Orange issue. This new serum dioxin assay will provide a precise measure of the current body burden of dioxin for each of the 2,010 men who contributed blood for this portion of the study. From this data, the investigators will be able to combine all of the study participants into a single-exposure analysis rather than the three occupation specific analyses currently used.

Another outcome of the serum analysis method is the estimation of the half-life of dioxin in humans. Initial calculations indicate that the half-life is approximately seven years.

6. Government interference in dioxin studies, especially in the peer review procedures, and the effects thereof:

Senator Daschle continues to express concern that there has been undue government and management interference with the conduct of the Air Force Health Study. Colonel Wolfe, Dr. Michalek and Dr. Albanese were clear in their letter to Senator Daschle in August 1987, as well as in their discussion with him in January 1988 and in their testimony on 12 May that there has not been any interference in their work. They have been free of interference throughout the study, and all decisions have been made on the basis of scientific merit. The Advisory Committee of the Agent Orange

Working Group provides review and oversight functions. Their advice and counsel has been extremely valuable to the study. Once they have approved a document or report, it is released by the Air Force Surgeon General in that form. At no time has there been technical direction of the study from non-scientific elements. The Air Force, through the Surgeon General's office, limits its management to administrative matters of funding, manpower and equipment. A statement was made in the Protocol of the Air Force Health Study (written in 1978 and 1979) that a committee should be established to provide scientific review of the study and guidance to the Air Force investigators. The suggested makeup of that committee included a "veteran's representative." The Protocol statements were written prior to the establishment of the Science Panel of the Agent Orange Working Group (AOWG) and were intended by the authors as a guide to the creation of an external review group. This suggestion was superseded by the creation of the Advisory Committee by the AOWG. The Air Force position is that membership on the Advisory Committee should be based primarily on scientific accomplishment and expertise. The Advisory Committee has periodically recommended modifications to preliminary versions of the study documents and reports. Changes made were made to address scientific issues raised during the review process.

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13 June 1988

Senator Alan Cranston
Chairman, Veterans Affairs' Committee
United States Senate, Hart Building, Room 112
Washington, DC 20510

Dear Senator Cranston:

In response to your letter dated 2 June 1988 (copy attached), the following are the answers to the questions you requested:

1A. "What is your estimate of the amount of Agent Orange exposure which the Ranch Handers received in Vietnam, including the percentage of Ranch Hand personnel so exposed and the average amount of time per day of exposure? Please indicate any differences in exposure based on occupation."

It is impossible for the Ranch Hand Vietnam Association to estimate the amount of exposure to the herbicides any single individual received during his tour in Vietnam. The scientific community has made those estimates based on the best description of the occupational environment of Ranch Hand personnel in consultation with veterans of Operation Ranch Hand. However, in an effort to put the job of the Ranch (the aerial application of herbicides in a combat environment) in perspective, we offer the following:

(Slides have been included to help with the written description.) Flight line personnel and aircrew had direct physical contact with herbicides every day in which they repaired, maintained or flew Ranch Hand aircraft. The chemicals were shipped to Vietnam in 55-gallon drums; trans-loaded into transfer tanks and by hose, pumped into the spray tank located in the cargo compartment of the C123 aircraft. Small amounts of spillage occurred during this process as indicated in the pictures. Some spillage occurred inside the aircraft during loading, in much the same way as spillage occurs when you put gasoline in your automobile at a gas station. Each day that a person had to fix, maintain or fly Ranch Hand aircraft, that person touched or otherwise came into direct physical contact with the herbicides. Maintenance personnel changed spray nozzles, nozzle diaphragms, spray pumps; repaired battled-damaged hoses, repaired enemy bullet holes in the spray tanks; and the flight crew flew the same aircraft with spillage on the cargo deck. Aircrew touched chemical dampened components during preflight inspection and flew those aircraft with those chemicals aboard. We don't wish to create the impression that the mission was conducted in a sloppy fashion. On the contrary, however, normal spillage occurred. The men of Operation Ranch Hand had direct contact with herbicides every day they worked on or flew Ranch Hand aircraft, or even entered a herbicide loading area. That was our job -- handling herbicides!

(With the advent of the blood serum assay detecting dioxin in the human blood, estimates of contact with herbicides by Ranch Hand personnel and its trace contaminate dioxin (0.0002%) is a mute point.) In 1978 the scientific community chose the Ranch Hand cohort for an epidemiology study with good reason and that decision has been further supported by the blood serum test for dioxin in the bodies of Ranch Hand personnel. The pilot study revealed the following:

Average Ranch Hand: 49 parts per trillion
High Ranch Hand: 313 parts per trillion
Average person in the streets of the
U.S.: 4 - 9 parts per trillion in his blood

In plain and simple terms Senator, Ranch Hand personnel touched, worked with, had eminent, frequent and regular physical contact with 95% of all the gallons of herbicides sprayed in Southeast Asia during that conflict in the same way as an artillery crew had eminent contact with his cannon and shell. Herbicides were our mission in Southeast Asia.

1B: "Were any safety precautions recommended by the Air Force with respect to handling Agent Orange? If so, were those precautions generally followed?"

No special safety precautions were recommended by the USAF. No special clothing was worn by any personnel handling, flying or otherwise dealing with herbicides. Operation Ranch Hand sprayed agricultural herbicides whose safety had been amply demonstrated and were in use worldwide to kill weeds.

2: "What are your organization's view regarding the comprehensiveness and scientific validity of the Air Force's Ranch Hand study?"

The Ranch Hand Vietnam Association has no scientists in the cohort of 1,265 veterans of "the Ranch". We have relied on the scientific community regarding questions of validity and comprehensiveness. It is obvious to the Ranch Hand Vietnam Association that the Air Force Health Study is a comprehensive and valid epidemiology study.

The scientific community has, from its inception, had high marks and respect for the methodology and conduct of the Air Force Health Study. Those who are criticizing the AFHS appear to be from a group not liking the conclusions thus far reached. It is the Ranch Hand Vietnam Association's desire, and the desire of veterans of Operation Ranch Hand, to see this study continued -- unaffected by politics -- and reach what ever conclusions the scientific data warrants. After all, the men of

Operation Ranch Hand were those most frequently in contact with herbicide Orange and all herbicides used by our nation in Southeast Asia.

The Ranch Hand Vietnam Association stands ready to assist you in any way it can to aid you in dealing with the herbicide controversy.

Respectfully,

Jack Spey

Jack Spey, Major, USAF(RET)
President
Ranch Hand Vietnam Association

Enc.

cc: Congressman G. V. Montgomery, Chairman,
House Veterans' Affairs Committee

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The American Legion

For God and Country

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June 14, 1988

Honorable Alan Cranston
Chairman
Committee on Veterans Affairs
United States Senate
Washington, DC 20510-6375

Dear Senator Cranston:

This is in response to your letter of June 2, requesting that we provide The American Legion's views on a series of questions emanating from the May 12, 1988 hearing on Agent Orange legislation and oversight issues.

1. Q. Please provide your organization's assessment of the Centers for Disease Control's Vietnam Experience Study results published in the May 13 issue of The Journal of the American Medical Association.

A. Following preliminary analysis of the findings of the Vietnam Experience Study, it appears that another study conducted by the Centers for Disease Control has been gravely flawed. The Vietnam Experience Study, which is the second of three studies that were to be carried out by CDC, was mandated by PL 97-72 as an expansion of the scope of the Agent Orange study that we discussed in detail during the hearing.

Section 401 of PL 97-72 states, in part, as follows: "In conducting such study, the Administrator may expand the scope of the study to include an evaluation of any long-term adverse health effects in humans of such service as such health effects may result from other factors involved in such service, including exposure to other herbicides, chemicals, medications or environmental hazards or conditions. The Administrator may also include in the study an evaluation of the means of detecting and treating adverse health effects found through the study."

Some of the major flaws are briefly highlighted below.

Dilution of Effects through Improper Exposure Definitions

The first flaw is that CDC has deliberately restricted itself to a vaguely defined generalized experience in Vietnam rather than focusing on the specific issues it was mandated to investigate, as set forth previously, which are the physical, chemical and psychological exposures of the Vietnam War.

By defining the "exposure" as a generalized "experience" in Vietnam, CDC has committed a classic flaw in epidemiological study design called the "dilution effect". That is, if the exposure is the general experience, then every person who served in Vietnam is defined, by design, to have been equally exposed to the chemical, physical or psychological hazard. Since approximately only I out of every 5 men who served in Vietnam was actually engaged in combat, any possible effects of the exposure will be diluted out when the "normal" experience of the 4 non-exposed men is averaged in. Let us say hypothetically that exposure to combat caused a doubling of the incidence of ulcers among the 20% exposed veterans, the effect would be obscured because 80% of the group being studied would not have been involved in combat and would have a normal background rate of the disease. Only extremely large increases in any disease rate could be discovered and reach statistical significance in a population so diluted.

The dilution effect caused by the inclusion of a majority of veterans with no exposure in the study population is compounded by the deliberate exclusion of some veterans who are likely to show health effects. By design, CDC eliminated veterans with multiple tours of duty in Vietnam, and anyone over the grade of E-5. Although this criteria is not as restrictive as that used in the Agent Orange study, in our opinion it is too restrictive, and damaging to the study.

It is extremely important to keep in mind that by and large, veterans in the 35-45 year old age group should be a healthy group of individuals. They were only admitted into the Armed Forces after passing rigorous physical and psychological examinations. Men in the 35-45 year old age group, as a whole, do not develop many diseases or disorders. Therefore, the prevalence of disease and disability in this group is expected to be low.

A knowledgeable epidemiologist, in our estimation, would try to optimize the chances of observing an effect by including, rather than excluding, the veterans who are most likely to have suffered from the exposures in question. This is one of the most simple applications of the concept of "statistical power", or the statistical ability to observe an effect if one is present.

CDC has thus committed two of the cardinal sins of epidemiology. The agency has diluted the study population through the inclusion of non-exposed veterans, and has decreased the statistical power of the study by eliminating those likely to have been exposed.

Biased Interpretation

In addition to a flawed basic design, CDC compounds its own error with an interpretive bias designed to obscure any results which indicate that a health or well-being problem exists among the veterans. In the analysis of the incidence of PTSD, CDC was forced to separate actual combatants from the other Vietnam-based troops. This is because the clinical definition of PTSD, as defined by the American Psychiatric Association's DSM III, requires a specific exposure to trauma.

When forced to stratify the study population, CDC found that the veterans who were exposed to the trauma of combat are indeed suffering from PTSD and other long-term psychological dysfunction. However, these findings are downplayed by CDC in the general conclusions as follows:

"These psychological problems, however, are not of a magnitude that has resulted in Vietnam veterans having as a group (emphasis added) lower social and economic attainment". This telling phrase is the key to recognizing the inherent bias in analyzing, interpreting and describing the results. It appears that the authors are intent on submerging or obscuring important effects by diluting the subgroups to which they pertain. In other words, in the body of the paper PTSD effects are found, but in the conclusion their importance is purposely downgraded.

There are also some other extremely important points that should be noted. It is our understanding that good research dictates that when an effect is found when the combat experience was taken into consideration, all previous findings should immediately be re-analyzed to see if they too may have been combat dependent. This was not done in the Vietnam Experience Study, nor did CDC differentiate among different levels of combat.

From some of the earlier studies on Vietnam veterans, it has made good scientific sense to hypothesize that the effects of the war would vary, depending upon the levels of combat experienced by the participants. This was one of the major conclusions of the first Congressionally mandated study on Vietnam veterans entitled "Legacies of Vietnam". Research projects since that time, including The American Legion's own Vietnam veterans study, have repeatedly confirmed this conclusion. We are not aware of any other researchers who have dealt with the issues of the Vietnam War and health, who have not taken actual combat into consideration in the basic study design. We do not know whether this was done through a lack of knowledge or a deliberate attempt to limit the possible findings. Whatever the original intent, the end result is that some major findings are missed.

Faulty Interpretation: Calling Positive Effects Negative

Despite flaws in the study design, the CDC data still show positive findings. That is, the Vietnam "experience" did adversely affect the health and well being of some Vietnam veterans. However, each time CDC came up with a positive finding, it was then interpreted to be either negative or wrong.

One example is the PTSD finding mentioned previously. It was a positive and important result - the importance of which was minimized.

Another is that one of the basic assumptions in the design of the study is that veterans are unreliable sources of information about their own health or their past medical history. On this basis, CDC justified an extremely expensive, cumbersome and inefficient study based on personal health examinations of selected veterans. In the May 13 report, CDC compares the health status of veterans obtained from a telephone interview to the health status from a physical examination. Not only were these data statistically indistinguishable, but where differences occurred, the trend was that the veterans had underestimated, rather than overestimated, various indicators of poor health. CDC should have emphasized this as an important finding. Instead the differences were described as recall bias, which undermines some findings of the study.

In the report on the Experience Study, the following "positive" findings were among those obtained in the case of those veterans who served in Vietnam:

a. Nearly double the rate of left ventricular hypertrophy

b. Greater hearing loss

c. Higher levels of GGT, thyroid stimulating hormone and glucose

d. Almost triple the rate of occult stool blood

e. Greater rate of evidence of post hepatitis B infection

f. Two of three sperm analyses significantly abnormal

g. One case of porphyria cutanea tarda, an extremely rate disease associated with herbicide exposure in the past.

None of these findings was discussed in any serious detail in the report. The abstract states that "few objective differences in physical health between the two groups" were found. This appears to be an attempt to minimize the findings.

With respect to another important area, when abnormal skin conditions as a whole were investigated, there was a large and significant increase in the rate of these conditions among those veterans who served in Vietnam. However, CDC, rather than considering this to be at least a highly suggestive, if not a definitive finding, proceeded to classify the skin conditions differently in a second table, which does not appear to be consistent with the first table, and thus turns a positive finding into a nebulous one. This is a particularly disturbing action since skin conditions should be considered, by objective researchers, as particularly important to evaluating toxic herbicide exposures.

Unjustified Refusal to Use Available Exposure Data

Any study of the effects of environmental exposures is limited by the extent to which one can define and quantify the exposure. In general environmental studies of water and air pollution, one is often forced to extrapolate regional or even national exposures from a relatively small number of actual measurements. In occupational environments many researchers must simply substitute number of years in a particular job classification for an actual exposure measure.

In the case of herbicide exposures during the Vietnam War, there is an extraordinarily comprehensive and valuable data set available for quantifying exposures. The U.S. Army and Joint Services Environmental Support Group (ESG) has carefully reviewed virtually all troop movement during the Vietnam War and has reduced this to a codified computer file.

ESG has also developed a Services HERBS tape which contains available records on backpack spraying, helicopter sorties, perimeter spraying, and wheeled vehicle missions. It also contains records of aborts, dumps and leaks that occurred during Operation Ranch Hand spraying missions, plus additional Ranch Hand missions that are not contained in the original HERBS tapes.

The use of this information in determining exposure for both the Agent Orange study which was previously mentioned, and for the Vietnam Experience Study, is vitally important. Although CDC has unilaterally declared that these data are not useful, the agency has not presented sufficient evidence or a logical reason that convinces us that the information contained in the Services HERBS tapes and the HERBS tapes is not useful.

We would like to point out that computerized methods for using this data as an exposure classification system exist, have been published in the peer reviewed scientific literature, and are in use in our own study of Vietnam veterans, as well as in several other studies and applications. This is not to state that one can evaluate precisely the extent of every veteran's exposure to herbicides. Rather, we are emphasizing that such an index is extremely useful for classifying veterans into major exposure probability categories such as not likely to have been exposed; low, medium and high exposure. Such stratification, when available, is of the utmost importance in study design. The failure to utilize an existing system in the CDC studies is a fatal flaw.

In the Agent Orange study, CDC did make an attempt to define exposure to herbicides by using a system which can only be regarded as simplistic for exposure classification. The Exposure Opportunity Index uses only a subjective evaluation of the likelihood of having been exposed to herbicides, without using the computerized spraying records. While chosing this simplistic approach, CDC rejected one of the most carefully developed and extensive records of any environmental exposure to be found anywhere in epidemiologic research.

2. Q. Does your organization have any concerns regarding the operation of the VA's Agent Orange Registry? Should the registry be updated for current addresses, and if so, how could that feasibly be done?

A. So far as we know, nothing is being done with the data contained in the Agent Orange Registry, which is unfortunate.

It would seem prudent to keep the addresses of the veterans in the registry current. At one time, those individuals received, on an irregular basis, an update on Agent Orange activities from the Veterans Administration. However, we have not seen copies of the publication for well over a year.

For those veterans receiving benefits, the addresses can be updated through the Target System. The others would obviously have to be secured from other sources such as the Internal Revenue Service.

3. Q. Is your organization satisfied with both the design of the VA Agent Orange medical examinations and the way they are conducted?

A. Early on in the Agent Orange examination program we received numerous complaints about the attitudes of examiners, problems in scheduling, etc. In about 1980 we began monitoring the program through the use of a questionnaire that was distributed nationwide, as well as through The American Legion's Department Service Officers and Field Representatives. When problems were spotted, we reported them to the VA Agent Orange Special Projects Office. Recently we have received no complaints.

4. Q. Without regard to the outcome of presumptive compensation legislation, does your organization see value in continuing ongoing Agent Orange research?

A. Yes. As we stated in our testimony, The American Legion holds fast to the position that it is the responsibility of the United States Government to use every resource available to determine the consequences of exposure to Agent Orange on those veterans who served in the Armed Forces in Vietnam, and then to adequately compensate those who are suffering from diseases and disabilities as a result of that exposure.

The American Legion does not subscribe to the statement made by a Veterans Administration official that Vietnam veterans complaining about the health risks of Agent Orange are suffering from a "mid-life crisis". Such a statement is irresponsible, and as far as we are concerned, the government has fallen far short of its responsibility on this entire issue.

Mr. Chairman, as always we appreciate your interest in the views of The American Legion.

Sincerely,

John Sommer

JOHN F. SOMMER, JR.
Director
National Veterans Affairs and
Rehabilitation Commission

Office of the
Administrator
of Veterans Affairs

Washington DC 20420

Veterans
Administration

JUL 1 1988

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find the Agency's response to the question which you submitted for the May 12, 1988, hearing by the Senate Veterans' Affairs Committee. Thank you for the opportunity to provide this additional information for the record.

Sincerely,

THOMAS K. TURNAGE
Administrator

Enclosure

cc: Honorable Frank Murkowski

"America is #1—Thanks to our Veterans"

Question: Please provide an accounting of all Federal money spent or obligated by any entity on research related to Agent Orange exposure, broken down by the sponsoring agency, including all expenditures for each study and the dates when the study was begun and completed. In providing the accounting for such studies currently underway or planned, please include the estimated completion date and costs.

Response: A special status report on Federal Agent Orange-related research is periodically prepared by the Science Panel of the Domestic Policy Council Agent Orange Working Group (AOWG). The most recent report dated September 1987 describes research, by Federal Agency, including target dates for initiation/completion of each and estimated funding. A report on total Federal Agent Orange-related efforts should emanate from the AOWG. We have been advised by the Executive Secretary, AOWG, that the U.S. Department of Health and Human Services will be responding to this request. The Executive Secretary has advised the Veterans Administration (VA) that this report was transmitted to the Chairmen and Ranking Minority members of the House and Senate Committees on Veterans Affairs in October 1987. This report includes VA conducted human and animal-related research with the exception of the following VA Proportionate Mortality Study follow-up research efforts:

Prop. Mortality Study Follow-up Research Efforts	Date Initiated	Projected Completion Date	Estimated Costs
o Military Medical Record Review	January 1988	Completed February 1988	$500.00
o VA Patient Treatment File (PTF) Review for Non-Hodgkins Lymphoma (NHL)	April 1987	December 1988	$-0-*
o A Retrospective Cohort Mortality Study of Marine Corps Vietnam veterans	November 1987	December 1990	$500,000
o A Separate Mortality Analysis for Army Veterans Stationed in I Corps in Vietnam in Vietnam Veterans Mortality Study	July 1987	September 1988	$-0-**
o Update of the Vietnam Veterans Mortality Study (VVMS)	October 1983	September 1988	$5,000

*The U.S. Army Environmental Support Group is abstracting military records for the Veterans Administration (VA) at no cost to the VA.

**VA "In-house" research not requiring additional funding.

VETERANS OF FOREIGN WARS OF THE UNITED STATES

OFFICE OF THE DIRECTOR

June 13, 1988

The Honorable Alan Cranston
Committee on Veterans' Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Please find enclosed the Veterans of Foreign Wars response to questions submitted by you with respect to testimony given during the recent Senate Veterans' Affairs Committee hearing on May 12, 1988.

With best wishes and kind regards, I am

Sincerely yours,

GORDON R. THORSON
Special Assistant
National Legislative Service

GRT/daa
Enclosure

QUESTION 1. Please provide your organization's assessment of the Centers for Disease Control's Vietnam Experience Study results published in the May 13 issue of The Journal of the American Medical Association.

RESPONSE 1. The results of CDC's Vietnam Experience Study held no surprises. The veteran community was already aware of the increase incidence of depression, anxiety, alcohol abuse and Post Traumatic Stress Disorder among in-country Vietnam veterans. Common sense dictates that these disorders would be more prevalent among soldiers who have experienced combat. In fact the Vet Center program was put in place to help treat these very same problems.

QUESTION 2. Does your organization have any concerns regarding the operation of the VA's Agent Orange Registry? Should the registry be updated for current addresses, and if so, how could that feasibly be done?

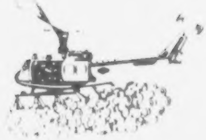
RESPONSE 2. We understand that current projections indicate that approximately 50 percent of addresses listed by Vietnam veterans on the Agent Orange register are now out-of-date. The VA could launch a public service news media campaign stressing the importance of the registry and encourage veterans to notify their local Veterans Administration Medical Center (VAMC) of any change of address. The Agent Orange registry was a worthy undertaking and efforts should certainly be made to keep the information up-to-date.

QUESTION 3. Is your organization satisfied with both the design of the VA Agent Orange medical examinations and the way they are conducted?

RESPONSE 3. We have had no problems with the current system of conducting Agent Orange medical examinations. However, we steadfastly believe that all current and future examinations should include a blood test or adipose tissue test specifically targeted to identify the veteran's current level of retained Dioxin 2,3,7,8,TCDD.

QUESTION 4. Without regard to the outcome of presumptive compensation legislation, does your organization see value in continuing ongoing Agent Orange research?

RESPONSE 4. Our written and oral testimony clearly states our position. Agent Orange research must continue until the scientific community can determine the effect Dioxin 2,3,7,8,TCDD has had on the human system.



VIETNAM VETERANS
AGENT ORANGE VICTIMS, INC.

205 Main Street
Stamford, Connecticut 06901

President
Frank McCarthy
Executive Director
James Sparrow
Secretary
Jane Dziedzic

Alan Cranston, Chairman
Committee on Veterans Affairs
United States Senate
Washington, D.C., 20510-6375

June 7,1988

Re: Follow-up questions to May 12, 1988 Hearing on Agent Orange

Dear Senator Cranston:

[Follow-up question number 1.] What is the status of the planned distribution of the settlement fund in In re "Agent Orange" Product Liability Litigation?

I will contact Chief Judge Jack B. Weinstein who presides over the litigation regarding this question in case there has been new developments in the case which I am not aware of. However, please refer to my written and oral statements before your committee on May 12,1988. Both statements address the fund distribution status. The main point is that the distribution of settlement funds (grown from \$180 million to \$235 million) can not begin until the appeals process is completed. Hopefully, the Supreme Court will issue those rulings during this term. Meanwhile, we exercise patience.

[Follow-up question number 2a] Does your organization have any concerns regarding the operation of the VA's Agent Orange Registry?

I must say that I was dismayed by VA Assistant Administrator Harvey's statements at the May 12, 1988 hearing regarding the VA Agent Orange registry. The fact that the VA would "have to go to the Post Office to up-date the registry list" is an indication of the VA's irresponsibility to those Vietnam Veterans and their families who are concerned about the adverse ill health effects from exposure to Agent Orange. Those Veterans should have been continuously provided with unbiased information regarding the Agent Orange issue. Instead, the VA let the list deteriorate and, more importantly, left those Veterans and their families without proper medical, scientific, legal or legislative information. This same practice continues today.

Further, our organization strongly supports the position that the VA has a moral and ethical responsibility to those Veterans and their families to inform, enlighten and educate them, on a continual basis, until the Agent Orange issue is resolved legally, scientifically, legislatively and medically, **no matter how long those issues continue to be unresolved. Unbiased information is the least we can do for those distressed Veteran families.**

[Follow-up question number 2b] Should the registry be up-dated for current addresses, and if so, how could that feasibly be done?

Toll Free 1-800-521-0198 In Connecticut 1-800-228-5940

In order to up-date the registry list, the VA, at this late date, will have to conduct a proper out-reach campaign comprised of direct mailings, media advertisements and coordination with existing Veterans organizations. A joint venture between the VA and the Agent Orange law suit settlement distribution fund could possibly solve the entire matter.

[Follow-up question number 3] Is your organization satisfied with both the design of the VA Agent Orange medical examinations and the way they are conducted?

No, we are not satisfied and we have complained about those examinations since the VA started that program. For more than a decade we have advocated a more thorough medical work-up of Veterans claiming ill health effects from exposure to Agent Orange. For years the VA disregarded our complaints and on October 25, 1982 the United States General Accounting Office (GAO) [enclosed] confirmed our complaints by issuing their report; " VA's Agent Orange Examination Program: Actions Needed To More Effectively Address Veterans Health Concerns ".

This report also confirmed our complaints that the VA provided little or no information on Agent Orange or the Veterans health and that the VA personnel were not well informed about the examination program. The report also recommended that the computerized registry be discontinued, stating; **"VA's computerized agent orange registry does not contain specific diagnosis of the health problems found in Vietnam Veterans. As a result, it cannot be used to determine if the veterans are experiencing an unusual incidence of chloracne or other skin conditions or show the types or locations of tumors or types of birth defects in their children. The VA has not included Veterans addresses in the registry".** Senator Cranston, we highly suggest that a copy of that entire GAO report be issued to all members of the committee.

It is our organizations belief that the VA has done little, if anything, to properly address the concerns of the Veterans claiming problems or concern about exposure to Agent Orange, before or after the release of the GAO report. Further, we believe that the VA has used the registry to advocate their political position that Agent Orange exposure causes no ill health problems other than the rash, chloracne.

The most disheartening aspect of the VA's medical examinations has been to deny Vietnam Veterans and their families medical examinations and treatment of the Veteran's children born with birth defects. The VA has adhered to the despicable position that they are legally unable to even examine the Veteran's children and unless Congress forces them to change that position, the VA couldn't and wouldn't do anything to help those children. Consequently, more than 64,000 Veteran's children suffering from a multitude of birth defects and disorders have been left to their own fates.

(continued)

Further, many of those children have birth defects and/or disorders which are, in fact, repairable. All that is necessary to repair or reverse the defect is the implimentation of existing treatment modalities or surgical operations. However, many more of those families do not have the insurance coverage or funds to pay the monitary costs. To date, we have found no federal or state programs which would cover those costs. Consequently, those children have been and currently are suffering a cruel form of discrimination, which has had a devastating adverse psychological effect upon the child as well as the parents.

Our organization has, for several years, tried to bridge the gap between those children and the help they so desperately need. We have, in fact, helped hundreds of children. However, there are tens of thousands more who we will never be able to help simply because we will never be able to raise the amount of money and/or resources necessary to help so many children.

The responsibility lies with all of American society, for they are our children. We as a nation must no longer look at those children in terms of whether their birth defects are a result of Agent Orange or not. We must look at them for what they are, children who need compassion and help and whose future, otherwise, is one of endless degradation, discrimination, ridicule and despair. They must no longer be permitted to be trapped in a void of political controversy. They must be afforded the opportunity to live as normal a life as our constitution allows. Their suffering must end and in order to end the suffering of each and every single child a cooperative effort on the part of all branches of government as well as other segments of the private and public sector must be achieved. If we do not do this, America will never heal the open wounds of the Vietnam War. We as a nation will forever be destined to suffer the devisiveness, controversy and guilt inflicted upon us by that war. **As long as those children suffer, America suffers!**

[Follow-up question number 4] Without regard to the outcome of presumptive compensation legislation, does your organization see value in continuing ongoing Agent Orange research?

In 1979 the VA was mandated to conduct research regarding Agent Orange. That same research was relinquished and brought under the control of the Centers For Disease Control (CDC) who just recently declared that they are unable to begin that research. Both agencies should bow their heads in disgrace for such obvious irresponsibility. One would think that in dealing with such an emotional and explosive issue as Agent Orange, those two agencies would be held accountable for their actions by the Congress. Instead, not even so much as a wrist slapping has occured. Consequently, on this matter, the Congress should bow its head in shame as well.

(continued)

After listening to the various government agencies testify during the May 12, 1988 hearings, the fact remains that nearly $100 million has been spent by the government for research regarding Agent Orange. If such a large amount of money has been spent and the results of that research can not determine if Agent Orange did or did not cause the ill health effects claimed by the Veterans, what value is possible for such research or any future research?

Perhaps an argument could be made for some value to future generations of humans who may be exposed to Agent Orange.

However, since 2,4,5-T and most other Dioxin related herbicides have been permanently banned by our Environmental Protection Agency (EPA) and 2,4-D, the other component of Agent Orange has demonstrated ill health effects from exposure, it is highly unlikely that there will be future human exposures to Agent Orange. We see little value for any research regarding Agent Orange which does not pertain to creating treatment to correct the problems experienced by the Veterans and their families.

For instance, the VA, CDC, EPA and even the Dow Chemical Company admit that exposure to Agent Orange causes the rash chloracne. The VA has denied most cases for compensation but has, in fact, paid several. Logic demands that if a Veteran is suffering from a service related illness (chloracne), treatment should be administered by the VA. There is no known cure for chloracne. Proper and necessary research would be to develop a treatment or cure for chloracne.

You must understand, Senator Cranston, that our organization sees little value in any measure which does not pertain to alleviating the ill health effects experienced by Vietnam Veterans and their families. Consequently, compensation measures and research designed to determine if the Veterans are suffering ill health problems from exposure to Agent Orange are low on our priority list.

Our priority has been to help the Veterans detect their cancer in time before it spreads throughout their body and becomes terminal. Again, the VA has denied the Vietnam Veterans basic cancer prevention information because, " we do not practice preventive medicine at the VA" I was told by Dr. Custice the former chief medical director of the VA.

Perhaps, if the VA would begin to practice preventive medicine, billions of taxpayer's dollars would not have to be used to treat long term in-patient care for the millions of Veterans who are statistically expected to contract various types of cancers in the near future, especially colon, testicular and other cancers which have a high cure rate and a relatively low cure cost rate.

Please review the enclosed Testicular Self-Examination Guide. For years this guide saved countless Veteran lives.

(continued)

The VA's central office condemned this guide calling it, "alarmist". However, VA hospitals throughout the nation bought and distributed the guide. We used the funds from VA hospital sales to print more guides which we distributed free to Vietnam Veterans and organizations throughout the nation. What a way to have to help Veterans, Senator. Think what we could have accomplished if the VA willingly assisted us with our anti-Cancer campaign.

The Vietnam Veterans suffering from the ill health effects from exposure to Agent Orange were exposed to a variety of chemicals which could have caused their ill health problems.

Those Veterans have been out of the exposure area for 15 to 23 years. They have been augmented back into American society and have been exposed to the same environmental, occupational and health factors as the general American population. It is medically and scientifically impossible, without an irrefutable method of determination, which does not exist at this time, to determine if Agent Orange caused the Veterans specific ill health problems or not.

Chloracne is the only illness claimed by the Veterans which does not abound in the general American population and is an irrefutable link to Dioxin exposure. Logic demands that if Vietnam Veterans suffer from chloracne than they should and do suffer from other ill health problems experienced by exposed forrest workers, farmers, industrial workers accidently exposed and animal experiments.

Further research designed to determine a causal relationship between Agent Orange exposure of Vietnam Veterans and long term ill health effects is both unnecessary and wasteful. Monies spent on research designed to create treatment, to repair the damage done to Veterans children suffering from birth defects and to compensate for Veterans disabilities are monies well spent and necessary.

In conclusion, Senator, I wish to thank you on behalf of our Board of Directors and the Vietnam Veterans and their families which comprise our organization for your years of service related to the Agent Orange issue. If our organization can be of further assistance to you or your Committe please feel free to contact us at any time.

Sincerely,

Frank McCarthy

Frank McCarthy, President: VVAOVI

Enclosures
cc: Chief Judge Jack B. Weinstein

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

VA's Agent Orange Examination Program: Actions Needed To More Effectively Address Veterans' Health Concerns

SUMMARY

Although the Veterans Administration's (VA's) agent orange examinations were more thorough than veterans perceived, GAO generally confirmed veterans' complaints that

--the examinations were not thoroughly conducted,

--VA provided veterans little or no information on agent orange or their health, and

--VA personnel were not well informed about the examination program.

VA could reduce dissatisfaction and concerns by providing veterans timely and thorough examinations and adequate information about agent orange and their health.

GAO makes several recommendations to improve program management and increase veterans' awareness of the agent orange-related services VA offers.

GAO/HRD-83-6
OCTOBER 25, 1982

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

VA'S AGENT ORANGE EXAMINATION PROGRAM: ACTIONS NEEDED TO MORE EFFECTIVELY ADDRESS VETERANS' HEALTH CONCERNS

DIGEST

Although the Veterans Administration's (VA's) agent orange examination program was intended as a response to Vietnam veterans' concerns about the potential adverse health effects of exposure to agent orange, veterans are generally dissatisfied with VA's efforts. Congressman Thomas Downey and Senator John Heinz requested that GAO determine the effectiveness of VA's efforts to assist veterans concerned about agent orange.

Since 1978, VA has provided examinations to over 89,000 Vietnam veterans. Although the examinations were more thorough than veterans perceived, GAO's evaluation of the examination programs at 14 of VA's 178 medical facilities generally confirmed veterans' complaints.

CLOSER MONITORING OF PROGRAM COULD REDUCE DISSATISFACTION

VA could reduce dissatisfaction and concerns by providing veterans timely and thorough examinations and adequate information about agent orange and their health.

About 55 percent of the 891 veterans responding to GAO's questionnaire were dissatisfied with their agent orange examination. Generally, veterans complained that

--their examinations were not thorough,

--VA provided them little or no information on the potential health effects of agent orange exposure,

--VA personnel did not show enough interest in their health, and

--they did not get an examination as soon as they wanted. (See pp. 5 and 6.)

Comparison of examination records with questionnaire responses for a random sample of 96 respondents, however, showed that the examinations were more thorough than the veterans perceived. (See pp. 6 to 8.)

Nonetheless, only 1 of the 14 facilities GAO visited was adequately following up on the health problems reported by veterans. Furthermore, only about 10 percent of the examination records documented a complete medical history, and only about 36 percent indicated that the physical examination covered all required body parts and systems. (See pp. 8 to 11.)

Two factors which may have contributed to the examinations' lack of thoroughness were the (1) poor design of the examination forms and (2) examining physicians' lack of familiarity with agent orange.

The medical history and physical examination forms did not list all factors to be covered including some health problems veterans have attributed to agent orange. (See pp. 11 and 12.)

Examining physicians at four facilities GAO visited were not familiar with VA circulars describing the agent orange program or the body systems on which the examination should focus. (See pp. 13 and 14.)

Environmental physicians at 6 of the 14 facilities GAO visited believed the examination program was of little or no use because no health effects of exposure to agent orange, except the skin condition chloracne, have been proven. (See pp. 14 and 15.)

VA's Office of Environmental Medicine had no program for monitoring the quality of agent orange examinations. (See pp. 15 and 16.)

VA SHOULD DISCONTINUE COMPUTERIZED AGENT ORANGE REGISTRY

VA's computerized agent orange registry does not contain specific diagnoses of the health problems found in Vietnam veterans. As a result, it cannot be used to determine if the veterans are experiencing an unusual incidence of chloracne or other skin conditions or to show the types or locations of tumors or types of birth defects in their children. (See pp. 23 and 24.)

VA has not included veterans' addresses in the registry. Thus, the registry is not meeting its two primary objectives--providing information on health problems experienced by Vietnam veterans and facilitating followup with veterans if necessary at a later time. (See pp. 24 and 25.)

VA's Inspector General identified extensive coding errors and duplicate records in the registry, which compromised its value and integrity and resulted in incorrect statistics. However, VA had not corrected the data or assessed the reliability of other data in the registry. (See pp. 25 and 26.)

Although the registry's deficiencies could be corrected, the corrections would be costly and the data still could not be used as a basis for scientifically valid conclusions about veterans' health. Discontinuing the registry but maintaining a list of veterans who have had agent orange examinations could save almost $1 million a year in administrative staff and computer costs. (See pp. 27 and 28.)

VA SHOULD DO MORE TO ALLEVIATE VETERANS' CONCERNS

Most veterans responding to GAO's questionnaire sought agent orange examinations because they were concerned that health problems, such as chloracne, cancer, and birth defects, may be caused by exposure to agent orange. Many veterans' dissatisfaction with what VA did for them appears to have resulted, in part, from a lack of understanding of the examination's limitations. (See pp. 30 and 31.)

VA could alleviate concerns by providing information on the kinds of skin problems, tumors, and birth defects identified in agent orange examinations. (See pp. 32 to 35.)

For example, VA could tell veterans that dermatologists at VA medical facilities have reported seeing only common skin problems, and that the Armed Forces Institute of Pathology has found few unusual tumors in tissue samples taken from Vietnam veterans. VA could also alleviate concerns by (1) informing veterans of the limitations of the agent orange examination, (2) providing examination results to veterans who have not received them, and (3) providing veterans available information on agent orange's potential for causing birth defects.

VA OUTREACH EFFORTS NOT EFFECTIVE

Agent orange informational materials prepared by VA were not reaching all veterans concerned about agent orange because VA had not effectively advised veterans of their availability. The lack of information provided by VA was the greatest source of dissatisfaction among veterans responding to GAO's questionnaire.

Although VA has prepared informational materials on agent orange, veterans could generally obtain these materials only at a VA medical facility, regional office, or outreach center. Moreover, when contacted by telephone most VA medical facilities did not (1) inform callers that the pamphlet was available at the facility, (2) offer to send it to callers, or (3) mention that they showed VA's agent orange film in their outpatient clinics. (See pp. 41 and 42.)

In contrast, three States and one VA medical center conducted outreach efforts, including public service announcements, which identified large numbers of veterans who wanted information about agent orange or an examination. (See pp. 42 to 44.)

DENIAL OF DISABILITY CLAIMS MAY PREVENT RETROACTIVE COMPENSATION

Ongoing epidemiological studies are likely to be the primary source of evidence to show whether disability compensation claims which veterans allege to be agent orange related were service connected. However, according to VA, veterans whose disability claims are eventually proven to be service connected based on the results of these studies would be limited by law to 1 year of retroactive compensation from the date of reconsideration rather than the date the initial claim was filed.

About 93 percent of the 14,236 agent orange-related disability claims filed by veterans as of July 1982 have been denied. Almost half of them were denied not because the claimed disability did not exist, but because there was no evidence in the veterans' service medical records or any other source that the disability was diagnosed or treated during the veterans' service. (See pp. 46 to 48.)

However, in Vietnam the treatment for health problems incurred in the field was generally not recorded in a soldier's service medical records. (See p. 48.)

RECOMMENDATIONS TO THE ADMINISTRATOR OF VETERANS AFFAIRS

GAO is making several recommendations to the Administrator to insure that veterans receive timely and thorough examinations and information about agent orange and their health. (See pp. 17, 28, 35, and 44.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress should consider whether 38 U.S.C. 3010(g) should be amended to extend the retroactive compensation period for agent orange-related disability claims to the date the claim was filed. (See p. 49.)

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AGENCY COMMENTS

While VA agreed with most of GAO's recommendations (see app. V), it offered a number of comments suggesting that GAO used old data and the problems were not as serious as GAO maintained. GAO generally disagrees with VA's assessment. VA offers little evidence to suggest that the deficiencies GAO identified have been corrected. GAO believes that action is needed to improve the agent orange examination program. (See pp. 17, 28, 36, 44, and 49.)

OTHER FACTORS!

Testicular cancer is RARE in middle aged and older men. However, other risk factors are:

1) If you have a family history of testicular cancer.
2) Male caucasians.
3) Men who have had viral infections or mumps which brought about atrophy of the testicles.
4) Men who had undescended testicles.

EXPLANATION OF TERMS

EPIDIDYMIS: *A soft, tube like structure on the back side of the testicles.*

TESTICLES: *Usually two egg shaped and somewhat firm organs located below the penis.*

SCROTUM: *A pouch of skin which holds the testicles.*

VIETNAM VETERANS
AGENT ORANGE VICTIMS, INC. (AOVI)

Design – Todd Neal • NYC

WHAT VIETNAM VETERANS SHOULD KNOW ABOUT TESTICULAR CANCER.

IT COULD SAVE YOUR LIFE!

This guide to Testicular Self-Examination is designed to provide you and your family with a step-by-step method of detecting abnormalities which could be Testicular Cancer. This guide will attempt to answer significant questions!

Veterans Administration (VA) and Department of Defense (DOD) records confirm the fact that most Vietnam veterans were exposed to various chemicals which scientific studies have shown to be highly carcinogenic. Agent Orange, Agent Blue and Dioxin are but a few. Swedish studies of Dioxin and exposed forest workers show a six fold increase in the risk of soft tissue sarcomas (cancer).

Regardless of whether you were exposed to these chemicals the fact remains—Testicular Cancer is the number one cancer killer in men of the same age group as the Vietnam veteran.

TESTICULAR SELF-EXAMINATION GUIDE

© Vietnam Veterans Agent Orange Victims, Inc. 1983 Frank McCarthy, President 27 Washington Square North, NY, NY 10011

WHAT IS TESTICULAR CANCER?

Testicular cancer is the most common cancer (solid tumor) in men between the ages of 15 & 40. It is also the number one cancer killer in men between the ages of 27 & 40, which is the average age of the Vietnam veteran. However, Testicular cancers are the most curable if they are detected and treated in their early stages before they can spread to other areas of the body. The most recommended method of detection is the TESTICULAR SELF-EXAMINATION!

The cancer itself is mostly confined to one testicle. The uneffected testicle will provide one with the capability of orgasm, erection, sexual fertility and a relatively normal life.

When a lump or tumor is found in one of the testicles it may not be cancerous. However, 96% of all tumors found in the testicles are cancerous. Most physicians agree that instead of removing the tumor the surgical removal of the testicle should be done in order to avoid the spread of the cancer. This, of course, depends upon the type of tumor and cancer.

Many patients have their testicular lymph nodes removed. After surgery, chemotherapy and radiation therapy are sometimes used and followup tests are conducted in order to check for the spread of the cancer.

WHEN SHOULD I CONDUCT A TESTICULAR SELF-EXAMINATION?

At least once a month. Make it part of your personal hygiene! The best time is during or just after a shower or bath. This is the time when the skin around the testicles is most relaxed.

WHY SHOULD I BOTHER?

Mostly, because it could save your life! The Self-Exam, done on a regular basis can greatly increase your chances of detecting abnormalities and testicular tumors and cancers.

Early detection of Testicular cancer makes it one of the most curable cancers. Without early detection, or, if you do not seek medical assistance immediately, it can be one of the most fatal cancers.

The Self-Examination will familiarize you with the normal consistency of your testicles so you are able to detect any abnormalities early.

WHAT ARE SOME OF THE SYMPTOMS OF TESTICULAR CANCER?

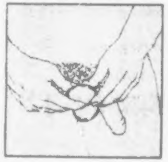
- Small painless lump on the testicles.
- Heavy feeling in the testicles.
- Dragging sensation in the groin.
- Pain could mean advanced cancer or other problems

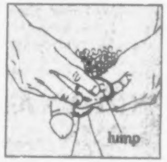
WHAT DO I DO IF I HAVE THESE SYMPTOMS?

See your physician immediately! These symptoms may not mean cancer! Many other problems in the male genitalia are confused with cancer. *See your doctor!* Only a physician can evaluate the abnormality. Do Not Panic, but, do not disregard the symptoms!

HOW TO CONDUCT THE TESTICULAR SELF-EXAMINATION.

While holding each testicle separately apply some pressure with the thumb and fingers of both hands.





If you see a lump or feel an area of firmness, stay calm, but, contact your physician immediately! If you do find anything abnormal most often it will be an area of firmness on the front or side of the testicles.

TESTICULAR CANCER AND YOUR MALE CHILD.

The testicles of a male child are formed near the kidneys. The testicles DESCEND to the scrotal sac approximately one month before birth.

However, a small percentage of children's testicles DO NOT DESCEND before one year of age. Testicular cancer is *40 times* more likely to occur in men whose testicles DO NOT DESCEND after they are 6 years old.

If you or your son have an UNDESCENDED TESTICLE contact your physician because a simple surgical technique can bring the testicle down into the scrotum and considerably DECREASE you or your child's chances of contracting testicular cancer.

Vietnam Veterans of America, Inc.
2001 S St., NW
Suite 700
Washington, DC 20009-1125

(202) 332-2700

June 17, 1988

Senator Alan Cranston
Chairman
Senate Committee on Veterans Affairs
SR-414 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Cranston:

This will respond to your follow-up question arising from the May 12 hearing on Agent Orange issues.

1. Please provide your organization's assessment of the Centers for Disease Control's Vietnam Experience Study results published in the May 13 issue of The Journal of the American Medical Association.

From our reading of the results of the morbidity part of the CDC's experience study, as published in the May 13 issue of The Journal of the American Medical Association, there are several indicators of problems for Vietnam veterans which were understressed in the JAMA article. The study was broken down into three parts; a psychological assessment, a physical health assessment and a reproductive effects assessment.

The psychological assessment results report that Vietnam veterans have an increased prevalence of psychological problems, including anxiety, alcohol abuse, depression, and Post-Traumatic Stress Disorder.

The CDC reports that Vietnam veterans' physical health is generally no worse off than non-Vietnam veterans, except for a couple of areas; specifically hearing loss and low sperm count.

The CDC reproductive effects assessment tells us the Vietnam veterans report more birth defects than non-Vietnam veterans, but that hospital birth records failed to confirm a higher rate of birth defects.

The CDC study is being described as showing that Vietnam veterans basically have no adverse health effects from Agent Orange, and that the only major differences between Vietnam veterans and non-Vietnam veterans is that Vietnam veterans have more psychological problems. However, several aspects of the CDC study should be noted that tend to indicate that the CDC results should not be used to make such sweeping statements about the health effects of Agent Orange.

1. There are still other studies that are ongoing concerning the health effects of the Vietnam experience and exposure to herbicides containing dioxin. The CDC should be constrained from making statements that this study definitively answers the questions regarding these two issues when there are other important studies by institutions that have not

been completed e.g., the CDC itself, the VA and studies associated with various Agent Orange commissions, and studies still under various ongoing institutional research protocols.

2. The CDC study does not examine the effects of exposure to dioxin. Absolutely no attempts were made in this study to evaluate the exposure to Agent Orange suffered by the Vietnam veterans involved. Therefore, no conclusions can be drawn regarding the health effects of exposure to dioxin from the results of this study.

3. The CDC conducted part of its study by doing telephone interviews of Vietnam and non-Vietnam veterans. The veterans' responses were verified by physical examination in only 42% of the cases. Based on these examinations, the CDC concluded that Vietnam veterans self-reported more health problems, but the physical examinations did not verify that they did suffer from more health problems. There is a danger that this conclusion is erroneous because a full 58% of the veterans interviewed were not examined. It is important to note that only 75% of the Vietnam veterans randomly selected to be examined actually participated and only 63% of the non-Vietnam veterans who were selected actually participated. It is possible that veterans who were in poorer health, or had other commitments, would not choose to travel to have a three day physical examination, thus skewing the results.

4. Simply because the CDC study does not at this time demonstrate a strong cause and effect relationship between dioxin exposure and current illnesses or pathological findings does not mean that such a relationship does not exist. The authors of the study fail to make this important point.

5. The CDC results released in the JAMA article only address a few select areas. It would be helpful for veterans groups and others to see results in the full range of areas examined.

6. The authors of the CDC study make the comment that their Agent Orange blood study showed that "few US Army ground troops had been heavily exposed to dioxin-containing herbicides." This is an irresponsible and misleading statement. In the Agent Orange Serology Study conducted by the CDC there were essentially no differences in the blood levels of dioxin in Vietnam veterans who they believed may have been highly exposed, based on examining military records (which have been continuously described as inaccurate), and veterans who they believe were not exposed. The study did not mention that there were several explanations for why the blood levels of dioxin were the same. For example, the military records were too inaccurate and the half life expectations of dioxin could explain why veterans heavily exposed to Agent Orange had lower dioxin blood levels than would have been recorded years earlier.

7. The CDC states that only 15% of the Vietnam veterans studied had ever suffered from PTSD and that 2% had experienced the disorder during the month before the examination. These numbers relate only to veterans meeting the full diagnostic criteria for PTSD. It is important to note that much higher percentages of Vietnam veterans had suffered at least some of the symptoms of PTSD. Again the actual examinations conducted were limited.

8. Confirmation of reported birth defects through hospital records carries the potential of missing many birth defects that were not initially recorded on the hospital records. Often, developmental birth defects do not become apparent until weeks, months, or longer after the birth of the child.

9. Even though the tables in the JAMA article show for the most part non-statistically significant differences between the two groups of veterans, the tables still show that Vietnam veterans as a group generally have more health problems. For example, in Table #3 (Cardiorespiratory Conditions Among Examination Participants), Vietnam veterans have a higher rate of conditions in nine of the eleven categories shown.

10. The CDC did not appear to give much weight to the fact that six Vietnam veterans had non-Hodgkins lymphoma vs. only one non-Vietnam veteran. Because three of the cases have not been confirmed yet, the CDC appears to be saying that these findings are not significant. In light of the fact that several studies have shown a relationship between dioxin and/or Vietnam service and non-Hodgkins lymphoma, we feel that the CDC's attitude toward this finding is inappropriate.

11. It is important to note that the CDC only checked a small, non-random sub-sample of birth records to confirm reported birth defects. It would have been preferable to examine all birth defects to ensure a more accurate result.

2. Does your organization have any concerns regarding the operation of the VA's Agent Orange Registry? Should the registry be updated for current addresses, and if so, how could that feasibly be done?

The VA's Agent Orange Registry is of significant concern to the VVA. In the event that the VA were to acknowledge that Agent Orange is the reason for a variety of diseases sustained by veterans having served in Vietnam, it may not be possible for the VA to contact these veterans, or their families, in the event that the veteran died as a result of an Agent Orange-caused disease. In this connection, the VA should maintain updated addresses for each individual listed on the registry. There are a variety of ways this might be accomplished. It is hoped that the question about how this might be feasibly done does not reflect a concern raised by the VA. If this is a VA expressed concern, perhaps the VA should examine its means for maintaining current addresses on virtually millions of individuals for whom it regularly provides benefits checks.

3. Is your organization satisfied with both the design of the VA Agent Orange medical examinations and the way they are conducted?

The VVA is dissatisfied with both the design and conduct of the medical examination given to veterans seeking to be evaluated on the basis of Agent Orange exposure. Typically, the exams are satisfactory but there is no consistency system wide in the thoroughness of the exams given. Additionally, the VA has failed to assemble and or evaluate the results of these exams to ascertain any common problems among those having been either treated or examined.

4. Without regard to the outcome of presumptive compensation legislation, does your organization see value in continuing ongoing Agent Orange research?

The VVA believes the scientific research on dioxin exposure should continue both with and without regard for the outcome of presumptive compensation legislation. As we asserted in our prepared statement for the hearing, it is inappropriate to await absolute scientific conclusiveness, as the VA prefers, before awarding compensation for disabilities likely to have resulted from exposure to dioxin.

5. In your testimony before the Committee's May 12 hearing, you state that the VA has improperly counted, in its reports of veterans treated for diseases associated with dioxin exposure, "many Vietnam veteran visits ... regardless of the veteran noting their concerns of an Agent Orange related illness". Please provide the documentation on which you base that statement.

The documents requested are attached.

As always, your attention to the views of the VVA is appreciated.

Sincerely,

Mary R. Stout
President

Department of Medicine and Surgery
Washington D.C. 20420

Veterans Administration

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DEC 1 4 1987

In Reply Refer To: (116A1)

Ms. Mary Stout
President
Vietnam Veterans of America, Inc.
2001 S Street, N.W.
Suite 700
Washington, D.C. 20009-1125

Dear Ms. Stout:

We appreciate your sharing with us the resolutions of the VVA Third National Convention related to health care. It is hoped that the following comments on several of the key issues raised in your letter will both identify some of our views on these issues and present a basis for further cooperative work between our two organizations.

Adequate funding for the treatment of Post-traumatic Stress Disorder (PTSD) has been a concern expressed by the Chief Medical Director's Special Committee on PTSD in its Annual Reports to Congress. The Department of Medicine and Surgery (DM&S) has acknowledged this concern and supports a review of PTSD funding by representatives of Mental Health and Behavioral Sciences Service and representatives of the Special Committee. In addition, the Consensus Conference on the effects of the DRG/RAM system in the VA, held the week of October 26, 1987, addressed the issue of DRG's and PTSD. The General Accounting Office (GAO) is currently conducting an audit of the effects of the RAM on several aspects of mental health care for veterans, including long term care, alcohol and other substance abuse treatment, and PTSD.

PTSD, like so many other mental disorders, is a chronic affliction. Specialized Inpatient PTSD Treatment Units, which are invaluable for providing some of the most severely disabled victims of PTSD with the beginning coping skills to manage PTSD, cannot be considered a definitive treatment for PTSD. Fiscal support must also be provided for the outpatient care needed by chronic PTSD sufferers. Initiatives such as the establishment of PTSD Treatment Teams as well as enhanced collaboration with Vet Centers and continued education of general psychiatry inpatient and outpatient staff in the diagnosis and treatment of PTSD are required and will be carried out.

The development of Program Guides for the treatment of PTSD in Specialized Treatment Units and on general psychiatry units will be completed in FY 1988. These guides should help to improve consistency and quality of care for veterans with PTSD. PTSD is a disorder which is often associated with other illnesses (co-morbidities) of which alcohol and substance abuse are among the most common. Clinical recognition of this fact by the VA's PTSD experts has resulted in the educational activities, begun in FY 87 and anticipated for continuation in FY 88, on the diagnosis and treatment of co-existing PTSD and alcohol/substance abuse.

"America is #1 — Thanks to our Veterans"

It is gratifying to note that the health care goals of the VVA, as expressed in the overall tenor of the resolution package as well as in particular items such as V-5-87, V-14-87, and V-6-87, are consistent with the goal of the Department of Medicine and Surgery to provide optimal services in terms of range and quality to our veterans. The "Means Test" legislation (P.L. 99-252) has expanded the population we may serve to include those in greatest need.

In terms of the development of alternative care options in mental health, the VA system provides a full range of service delivery settings including in-patient, mental hygiene clinic, day-hospital and day-treatment center. Extensive outreach and counseling care for PTSD and other readjustment problems in Vietnam veterans are provided by Vet Centers, with well-developed collaboration between that service delivery element and mental health programs at medical facilities. The presence of medical and surgical services within the same VA Medical Center and outpatient facilities provides an opportunity for truly holistic health care that is hard to find even in the private sector. Several innovative projects are currently underway that will expand even further the alternative mental health care options available. In VA Region 1, two projects have been initiated. ($3 million for an eleven-site demonstration project in New England and New York and $1.2 million for Puerto Rico.) The projects are specifically designed to help patients who have been prone to chronic readmission to maintain themselves in the community successfully. Also, Mental Health and Behavioral Sciences Service is interested in promoting vocational rehabilitation and compensated work therapy as components of an overall thrust of rehabilitation for chronically mentally ill veterans. We also hope to develop some medical psychiatric programs so that patients who suffer from both kinds of disorders can receive the most comprehensive care possible. We are sensitive to the unique needs of our increasing female veteran population and encourage programs designed to meet those needs.

VVA's support for the Homeless Chronically Mentally Ill (HCMI) Veterans project is appreciated. It is gratifying to note that P.L. 100-71 has extended the VA's authority for this program to September 30, 1988 and has provided $5 million in funding. In addition, this legislation authorized the establishment of homeless projects in selected Domiciliary sites; Mental Health and Behavioral Sciences Service and the office of Geriatrics and Extended Care (which oversees the Domiciliary system) are actively cooperating on this aspect of the HCMI program. The halfway house suggestions of item V-3-87 are similar in concept to what Mental Health and Behavioral Sciences Service is planning; namely housing placements for chronically mentally ill veterans engaged in compensated work therapy and social skills rehabilitation programs.

VVA's recognition of the efforts of Dr. Blank and Readjustment Counseling Service is appreciated by that Service and by the rest of DM&S. Support for the Vet Centers and their outreach and counseling activities will continue.

The Agency agrees that the relationship between dioxin (Agent Orange) exposure and its adverse health effects continues to be a major area of concern and effort. Unfortunately, it is often uncertain who were exposed to dioxin during their Vietnam experience. The VA has a multi-faceted program to assist veterans who may have been exposed to dioxin in Vietnam. A number of research efforts are underway to discover what the health effects of dioxin exposure and other factors of the "Vietnam experience" may be. The VA is working with several other Federal agencies (Centers for Disease Control, Environmental Protection Agency, Armed Forces Institute of Pathology and others) on some of these studies. The VA also is an active participant in the White House-established Domestic Policy Council, Agent Orange Working Group, which oversees and monitors Agent Orange-related efforts Government-wide.

The VA regularly publishes the Review of Literature on Herbicides, including Phenoxy Herbicides and Associated Dioxins, which contains an analysis and annotated bibliography of world literature on this subject. Ten volumes of this report have been published to date. The VA also gathers information on Vietnam veterans through the Agent Orange Registry program, which provides free medical examinations at all VA medical facilities for Vietnam veterans worried about the effects of Agent Orange exposure. Approximately 225,000 Vietnam veterans have participated in this program. In addition to the examination program, the VA has a priority treatment program for Vietnam veterans for conditions possibly related to Agent Orange exposure. Disability compensation is provided for injuries and illness incurred in or aggravated by military service. A veteran need not prove that Agent Orange specifically caused the disability in order to be eligible for compensation from the VA.

Regarding resolution P-1-87, while the Federal Government has made major efforts in these areas, some states have made significant contributions to our efforts to learn more about the possible effects of Agent Orange exposure on Vietnam veterans or to add to the available information on the effects of the "Vietnam experience" on these veterans. Some states have also been helpful to Vietnam veterans by sharing information about benefits and services provided by the VA. We applaud these contributions. To the extent that the new proposed National Association of State Agent Orange Programs can facilitate these efforts, it also has our support and approval. As the veteran's principal advocate, we will support any changes in compensation that are consistent with scientific evidence.

With regard to the question of Agent Orange coding in VA Medical Centers, the "AO" designation on the Patient Data Card (PDC), is a local facility option used as an identification for Vietnam veterans claiming exposure to Agent Orange. All veterans claiming exposure to Agent Orange are now exempt from completing a financial work-sheet to determine the ability to pay for their medical care. The "V" modifier on the PDC indicates that the Agent Orange survey questions need to be answered on each outpatient visit. Several mechanisms are being implemented to insure that the designation of veterans with "AO" status is accurate and does not result in distorted numbers of veterans reported in this status. Medical Administration Service has held several national conference calls and instituted a manual change telling field staff that if a veteran presents with "AO" or "V" on their PDC, a determination must be made on every outpatient visit whether or not the care rendered on that visit was related to Agent Orange exposure.

We trust the above comments are helpful. Your interest in quality health care for our veterans is appreciated. It is our hope that our two organizations will continue to work cooperatively towards this common goal.

Sincerely,

JOHN A. GRONVALL, M.D.
Chief Medical Director

Department of Medicine
and Surgery

Washington D.C. 20420

Veterans
Administration

SEP 21 1987

In Reply Refer To 136F

Mr. Thomas A. Sherwood
Director for Health Policy and Planning
Vietnam Veterans of America, Inc.
2001 S Street, N.W.
Suite 700
Washington, DC 20009-1125

Dear Mr. Sherwood:

This is in reply to your letter concerning the proper disposition of Agent Orange visits.

We are revising the outpatient portion of the manual. We have included instructions to the field indicating that a code showing possible exposure to Agent Orange on the patient data card is not an indication to automatically disposition the veteran's outpatient visit in the special survey as requiring care for exposure to Agent Orange.

If you have any further questions, please contact Karen O. Walters, Chief, Policies and Procedures Division at 233-2143.

Sincerely,

MICHAEL M. LAWSON
Director
Medical Administration Service

Vietnam Veterans of America, Inc
2001 S St., NW
Suite 700
Washington, DC 20009-1125

(202) 332-2700

August 25, 1987

To: Mr. Michael M. Lawson
Director, Medical Administration Service (MAS)

Thru: Dr. Daniel Winship, M.D.
Assistant Deputy Chief Medical Director
for Programs and Operations

Dear Mr. Lawson:

This letter is in response to Mr. R.E. Lindsey's letter of July 31, 1987 in which Chiefs of Medical Administration Service at the Medical Center level "were requested to review procedures for collecting special survey information with their clerks and to remind them (the clerks) that a code on the patient data card for Agent Orange (A/O) exposure is not to be used to disposition visits in the A/O survey."

If you recall this was triggered by my letter to you in which we noted that in some Medical Centers A/O visits were being dispositioned as regular ambulatory visits; in other Medical Centers regular ambulatory visits were being dispositioned as A/O visits because "A/O" was coded on the client's patient data cards, and that in still other Medical Centers combinations of both procedures were being carried out.

We are very thankful for the rapid response you took in trying to correct the problem. Unfortunately, we find that inspite of the Hot Line of July 15, 1987 to the Field, the confusion still exists. We are clear that many clerks, the folks who must implement the A/O Survey, inspite of computer assisted instructions, are still dispositioning interchangeably A/O and non A/O visits and are not under a clear organized centrally directed policy regarding this issue.

Any action, including the establishing of a written policy, you can direct in the Field to clear up the dispositioning problem relative to the logging of A/O and non A/O visits will be greatly appreciated.

Sincerely,

Thomas A. Sherwood
Director for Health
Policy and Planning

Mr. Rick O'Dell
Vice President

Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420

Circular 10-87-8

February 17, 1987

TO: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, and Regional Offices with Outpatient Clinics (11/136)

SUBJ: Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 10-0102

1. PURPOSE: This is a revision of DM&S Circular 10-85-29 which has been reformatted and includes the following changes:

- Quality Control of Follow-up Letters (Page A-4)
- Reporting changes to Environmental Physician Listing (Page A-4)
- Reporting of Follow-up Examinations (Pages C-1 "NOTE" and D-1)

2. POLICY: The Agent Orange issue continues to be a concern to Vietnam veterans and the general public. As such, it continues to receive media attention. The VA remains in the forefront of this issue and plays a leading role in supporting scientific and educational initiatives in an effort to provide all concerned veterans with the information and guidance they need as well as any medical care for which they are eligible.

The AOPO (Agent Orange Projects Office) has the responsibility to coordinate and monitor all DM&S activities, research and otherwise, relating to the Agent Orange issue. All policy and clinical questions relating to the potential effects of herbicides should be referred to this office (FTS: 653-5047). Questions relating to eligibility of veterans or treatment of active duty personnel should be referred to Medical Administration Service (136) VACO.

3. ACTION: The Agent Orange Registry, which consists of physical examinations and maintenance of a computerized index of those examinations, remains an important function of the VA. This registry is managed centrally by the AOPO. It remains our most effective means of identifying concerned Vietnam veterans. The importance of the role of each Environmental Physician and Medical Administration Service employee, beginning with the initial contact, in providing physical examinations, necessary treatment, advising the veteran of the results of the examination, and submitting properly completed codesheets, cannot be over-stressed.

THIS CIRCULAR EXPIRES ON FEBRUARY 16, 1988

It is important to keep in mind that information in the registry is not necessarily representative of the entire Vietnam veteran population, nor does it include all of the veterans who have been examined in the special Agent Orange program. All examination data are not in the registry because information from examinations conducted during initial program implementation are not included. Furthermore, there is a lag time between the date of examination and the processing of examination results at the Data Processing Center. Accordingly, analyses used in speeches or presentations should be qualified, with these limitations in mind, to avoid misleading or misinforming the audience.

Guidance for the Agent Orange Registry process is provided in the attachments.

4. **REFERENCES:**

a. DM&S Circular 10-86-28, Termination Of Special Registry at Armed Forces Institute of Pathology for Vietnam Veterans with Possible Exposure to Herbicides.

b. M-1, Part 1, Chapter 5, Medical Records.

c. M-1, Part 1, Chapter 15, Charges and Payments for Medical Care.

d. M-2, Part 1, Chapter 29, Change 78, Female Veterans.

e. MP-6, Part XVI, Supp. No. 4.1, Chapter 2, Patient Treatment File.

f. ICD-9-CM, Code books.

g. Records Control Schedule 10-1, Section XXII, Item No. 136-5.

5. **RESCISSIONS:**

a. DM&S Circular 10-85-29, Possible Exposure of Veterans to Herbicides During the Vietnam War, RCS 10-0102.

b. DM&S Circular 10-85-190, Environmental Physicians Roster, RCS 10-0076.

6. **FOLLOW-UP RESPONSIBILITY:** Director, Agent Orange Projects Office (10X2).

Arthur J. Lewis MD

ARTHUR J. LEWIS, M.D.
Acting Deputy Chief Medical Director

Attachments

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Circular 10-87- 8
February 17, 1987

ATTACHMENT A

GUIDELINES TO BE INCORPORATED INTO LOCAL AGENT ORANGE REGISTRY PROGRAM POLICIES

1. ELIGIBILITY CRITERIA:

Any veteran, male or female, who had active military service in the Republic of Vietnam between 1962 to 1975, and is expressing a concern relating to exposure to herbicides, is encouraged to participate in the registry which includes a thorough medical examination. In addition, any eligible Vietnam veteran currently receiving treatment in a VA medical center and/or outpatient clinic, will be provided the opportunity to participate in the AOR (Agent Orange Registry).

NOTE: A veteran who did not serve in Vietnam is not eligible for the Agent Orange examination.

For the purpose of this circular, any veteran who served in Vietnam, regardless of length of service (i.e., 1 hour, 1 day, 1 month, 1 year, etc.), is entitled to the AOR examination. Such individuals may have been permanently assigned elsewhere during the period of the Vietnam Conflict, (e.g., Cambodia, Thailand, Japan, at sea, etc.); however, the crucial factor is that individual's physical presence "in-country." Exposure to Agent Orange or any of the other classes of herbicides used elsewhere other than Vietnam, does not confer eligibility for purposes of the AOR.

The protocol for conducting the physical examination and ordering diagnostic studies is contained in Attachment B.

2. PROGRAM MANAGEMENT AND RESPONSIBILITIES:

In order to keep abreast of current information and program activities, Environmental Physicians and appropriate MAS personnel should be familiar with various materials distributed by VACO. Attention is directed to a recent videotape entitled, "Agent Orange Registry Program for MAS Personnel". This videotape should be accessible to all staff and can best be utilized in orienting new employees to policies and procedures. In addition, all program officials should attend the bi-monthly Agent Orange conference calls from VACO.

Environmental Physicians (or designee) and MAS staff play a most significant role in determining the perceptions Vietnam veterans have concerning the quality of VA health care services and of their individual treatment by VA health care providers. In this role, these individuals are responsible for carrying out the following main elements of the Agent Orange Registry Program:

a. Pre-Examination Activities

(1) Scheduling - Facilities should make every effort to give veterans Agent Orange examinations within 30 days of the request date. Consideration should be given to offering the examination on weekends or evenings to further convenience veterans.

(2) Information Dissemination - It is important that each veteran be fully advised of the limitations of the AOR examination. The examination cannot detect the presence of dioxin in the body nor determine whether adverse health effects or potential defects are related to exposure to Agent Orange. Your consideration of the best way to accomplish this communication process is highly encouraged. The following alternatives might be considered:

(a) Provide each Vietnam veteran reporting to the Outpatient/Admission area with a handout describing the purpose of the examination and its limitations. This can be further clarified by the examining physician during the course of the physical examination, preferably prior to beginning the physical examination process.

(b) Provide each veteran with the opportunity to view the audiovisual "Agent Orange: A Search for Answers." Veterans and/or visitors to VA health care facilities should be informed concerning the film and when and where it can be viewed.

(c) Copies of VA Agent Orange pamphlets will be provided to all telephone callers requesting Agent Orange information. In addition, these pamphlets and other informational material should be displayed in prominent areas (outpatient clinics, admission areas, etc.) to ensure availability to Vietnam veterans and other interested individuals.

(3) Card File - A card file will be established to include all registry participants. Each card prepared should include veteran's full name, address, telephone number, date of birth, social security number, date of initial examination and date(s) of subsequent follow-up examination.

(4) Codesheet Completion - A designated Medical Administration Service employee will be available to assist a veteran in completing VAF 10-9009 (in accordance with instructions in Attachment C, Figures 1 and 2) and to ensure that all information has been provided before the veteran is referred to the clinician for the examination. If the veteran has difficulty completing the form, the employee will provide assistance by entering the responses in each segment. To further ensure the form's completeness, the clinical examiner will review it and, if necessary, enter missing items at the veteran's direction.

b. Post-Examination Activities

(1) Medical Consultation - The Environmental Physician or designee will personally discuss, with each veteran examined, the results of the examination and the laboratory studies which are available at the time the physical examination is completed. This personal interview will be conducted in such a way as to encourage the veteran to discuss health concerns as well

as those of family members as they relate to exposure to herbicides, and will be documented in the veteran's medical record. Results which are not available at the time of the examination will be routinely included in the follow-up letter to the veteran. [Refer to 2.b.(3) "Follow-up Letters"].

(2) Records Review - The Environmental Physician will review the records of every Vietnam veteran examined to ensure that a complete physical examination was performed and documented.

(3) Follow-up Letter - In addition to the personal interview, the Environmental Physician will ensure that appropriate follow-up letters have been signed and forwarded to the veteran, explaining the results of the examination and laboratory studies. Follow-up letters will be mailed to the veteran within two weeks of the initial examination appointment. The only exception to this timeframe will be the case when a consultation at a specialty clinic is requested as part of the initial examination process. This exception suspends but does not remove the requirement for the follow-up letter. It should be sent not later than two weeks after the consultation.

It is the responsibility of the Environmental Physician to personally ensure that appropriate follow-up letters have been signed and forwarded to the veteran in a timely manner. A copy of this letter will be filed in the veteran's record.

It is essential that this letter be written in language that can be easily understood by the veteran. Inappropriate wording could unduly alarm or confuse the veteran. A great deal of sensitivity and care should be exercised in the preparation of this correspondence.

If the veteran examined has no detectable medical problems, the follow-up letter should so indicate and suggest that the veteran contact the VA in the event that health problems later appear. If it is determined upon examination that the veteran does have medical problems, it is not necessary to specify the problems in the letter. However, the veteran should be advised in the letter that the recent examination indicated a health condition/problem which may require further examination and/or treatment. If the veteran is eligible for VA medical treatment, the letter should so state and provide a contact point, including telephone number, within the facility. If the veteran is not eligible for treatment, the letter should so advise and recommend that veteran seek appropriate medical care elsewhere.

The letter should explain that the problem(s) is(are) not necessarily related to possible Agent Orange exposure. The letter should further explain that there is considerable research underway to learn more about the possible long-term health effects of Agent Orange exposure and that, at present, there is no conclusive scientific evidence that Agent Orange has caused long-term medical problems in Vietnam veterans or their children.

It is important that each letter be personalized. The VA has a personal interest in each veteran participating in the AOR program, and this should not be conveyed in a "form letter." These veterans deserve personalized assistance, not only during the course of the examination, but attention which is reflected in the follow-up letter as well.

3. REPORTING REQUIREMENTS:

a. Codesheet Submission - A monthly submission of codesheets will be made to the Austin Data Processing Center (DPC) according to the mailing schedule. [Refer to Attachment C, page C-10].

b. Monthly Statistical Report - This statistical report will be prepared on a monthly basis sufficiently in advance to ensure arrival in VACO by the tenth workday of the following month (send original only - copies are not required). Negative reports are required. In the preparation of data submissions, every effort should be made to ensure that accurate statistics are reported. Statistics for Satellite OPC's performing Agent Orange examinations should be included with the parent facility totals and not reported separately. [Refer to Attachment D for instructions in completing the monthly report and reporting format illustration Figure 4].

c. Quality Control of Follow-Up Letters - The AOPO will select medical facilities from each Region each quarter for quality review of follow-up letters. Selected facilities will be directed, at or near the beginning of each quarter, to send to AOPO copies of all the follow-up letters sent to veterans who receive the AOR examination during that quarter.

All copies should be legible and should contain the date the letters were mailed to the veterans. The date the veteran received the initial examination should be indicated in pencil in the upper right corner of the copy. The number of letters submitted to AOPO should correspond to the number of initial examinations reported on the monthly statistical reports for that quarter. If there is a deviation, the reason should be provided in a transmittal letter. The transmittal should also report any other difficulties encountered in the completion of follow-up letters. The AOPO staff will review all submissions to ensure compliance with stated requirements. Any problems will be reported to appropriate medical center officials.

The copies should be consolidated at the facility and sent to the following address: Agent Orange Projects Office (10X21), ATTN: Agent Orange Registry Coordinator, VA Central Office, 810 Vermont Avenue, N.W., Washington, D.C. 20420, no later than fifteen (15) workdays following the end of the quarter.

d. Environmental Physician Listing - A listing of Environmental Physicians is maintained by the AOPO. In an effort to keep this listing current, facilities are requested to notify the AOPO of any changes in the status of the primary and alternate Environmental Physicians at their respective facilities and/or satellite clinics. As change in designation occur, please submit in writing the name, title, mail routing symbol, FTS telephone number and the commercial telephone number including area code, to the Agent Orange Projects Office (10X21), ATTN: Agent Orange Registry Coordinator, VA Central Office, 810 Vermont Avenue, N.W., Washington, D.C. 20420.

Circular 10-87-8
February 17, 1987

ATTACHMENT B

PROTOCOL FOR CONDUCTING THE PHYSICAL EXAMINATION & ORDERING DIAGNOSTIC STUDIES

1. It is essential that a complete medical history, physical examination and interview be performed and documented, by/or under the direct supervision of the Environmental Physician, on appropriate forms.

2. The person actually performing the physical examination will be identified with the signature and title (M.D., P.A., etc.). If the examiner is other than a physician, a physician's countersignature is required, preferably the Environmental Physician.

3. When an Agent Orange examination is done as part of a compensation and pension examination, the physical examination will be done by/or under the direct supervision of the Environmental Physician.

4. Special attention will be given to those organ/systems alleged to be most frequently affected by exposure to herbicides containing TCDD. Particular attention will be paid to the detection of chloracne, a skin condition which has been associated with acute exposure to TCDD and other dioxins.

5. Evidence will also be sought concerning the following potentially relevant symptoms or conditions:

- altered sex drive
- congenital deformities among children
- neoplasms, including soft tissue sarcoma and lymphoma/non-Hodgkin's lymphoma
- repeated infections
- sterility
- difficulties in carrying pregnancies to term.

6. In gathering these data, it is important to determine and record the time of onset of the symptoms or conditions; their intensity; the degree of physical incapacitation; and the details of any treatment received.

7. Each veteran will be given the following baseline laboratory studies:

- chest x-ray (if one has not been done within the past 6 months)
- complete blood count
- SMA-6, SMA-12, or equivalent blood chemistries and enzyme studies
- urinalysis

a. Appropriate additional diagnostic studies should be performed and consultations obtained as indicated by the patient's symptoms and physical and laboratory findings.

b. Non-routine diagnostic studies, such as sperm counts, should be performed only if medically indicated.

NOTES: (1) Submission of pathological material to the Armed Forces Institute of Pathology is no longer required as indicated in DM&S Circular 10-86-28.

(2) The relationship between TCDD levels in blood serum and/or adipose tissue and Vietnam veterans' exposure to Agent Orange is being studied by several laboratories equipped to perform this highly specialized and complex analysis. VA medical centers are not equipped to perform this analysis, and will not perform any surgical or other procedure to obtain blood or tissue for the purpose of TCDD analysis without specific prior approval by VACO.

CIRCULAR 10-87-8
SUPPLEMENT NO. 2
August 21, 1987

TELEGRAPHIC MESSAGE

NAME OF AGENCY VACO WASHINGTON DC	PRECEDENCE ACTION P INFO	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED 8/18/87	TYPE OF MESSAGE ☒ SINGLE ☐ BOOK ☐ MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME ELAINE M. MORROW	PHONE NUMBER 233-4118	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

DIRECTORS, ALVAMC AND REGIONAL OFFICES WITH
OUTPATIENT CLINICS (REGIONAL DIRECTORS)
& (MEDICAL DISTRICT DIRECTORS)

00/136 THIS IS SUPPLEMENT NO. 2 TO DM&S CIRCULAR 10-87-8 (DTD: 8-21-87)

SUBJ: AGENT ORANGE COORDINATORS

1. PURPOSE: THE PURPOSE OF THIS ONE-TIME REPORT IS TO REQUEST ALL VA HEALTH CARE FACILITIES PROVIDING AO (AGENT ORANGE) EXAMINATIONS TO VIETNAM VETERANS TO IDENTIFY AN AOC (AGENT ORANGE COORDINATOR).

2. POLICY: THE AOC WILL SERVE AS THE PRIMARY ADMINISTRATIVE CONTACT POINT WITHIN EACH FACILITY'S MAS (MEDICAL ADMINISTRATION SERVICE) FOR VA CENTRAL OFFICE, AOPO (AGENT ORANGE PROJECTS OFFICE) STAFF.

3. ACTION:

A. AN AOC WILL BE RECOMMENDED BY THE CHIEF, MEDICAL ADMINISTRATION SERVICE AND APPROVED BY THE DIRECTOR AT

PAGE NO	NO OF PGS	SECURITY CLASSIFICATION
1	5	

CIRCULAR 10-87-8
SUPPLEMENT NO. 2
August 21, 1987

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION: INFO:	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME	PHONE NUMBER	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

EACH FACILITY HAVING AN AO PROGRAM. AOC DESIGNATIONS SHOULD REACH VA CENTRAL OFFICE BY SEPTEMBER 30, 1987, VIA FACILITY LETTERHEAD OR TWX.

B. PROVIDE NAME, ADDRESS, ROUTING SYMBOL, FACILITY NUMBER, AND FTS AND COMMERCIAL (INCLUDING AREA CODE) TELEPHONE NUMBERS. THIS INFORMATION SHOULD BE SENT TO:

VA CENTRAL OFFICE
ATTN: AGENT ORANGE REGISTRY COORDINATOR
AGENT ORANGE PROJECTS OFFICE (10B/A01)
WASHINGTON, D.C. 20420

C. THE AOC WILL BE RESPONSIBLE FOR COORDINATION OF OVERALL ADMINISTRATIVE AO ACTIVITIES AT THE FACILITY LEVEL. DUTIES OF THE AOC INCLUDE THE RECEIPT OF ALL AO RELATED INQUIRIES, ENSURE PAMPHLETS ARE PROVIDED TO VETERANS, SCHEDULE AO EXAM APPOINTMENTS, ESTABLISHING AND MAINTAINING ALPHABETICAL CARD FILES, COMPLETION OF VAF'S 10-9009, AGENT ORANGE REGISTRY CODESHEET, PROVIDING EACH

PAGE NO.	NO. OF PGS.	SECURITY CLASSIFICATION
2	5	

CIRCULAR 10-87-8
SUPPLEMENT NO. 2
August 21, 1987

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION: INFO:	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME	PHONE NUMBER	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

VETERAN WITH THE OPPORTUNITY TO VIEW AO AUDIOVISUALS.

D. THE AOC WILL ENSURE REGISTI[illegible] STATISTICS ARE ACCURATE ON THE MONTHLY STATISTICAL REPORT (RCS 10-0102) SENT TO VA CENTRAL OFFICE, CODESHEETS ARE COMPLETE BEFORE THEY ARE SENT TO THE DPC, FOLLOW-UP LETTERS HAVE BEEN SIGNED AND FORWARDED TO THE VETERAN WITHIN THE TWO-WEEK REQUIREMENT, CODESHEETS RETURNED FROM THE DPC HAVE BEEN ACCEPTED INTO THE REGISTRY BY VERIFYING MICROFICHE AND THAT ANY CORRECTED CODESHEETS ARE RESUBMITTED TO THE DPC.

E. THE AOC WILL BE RESPONSIBLE FOR OTHER MISCELLANEOUS AO ISSUES AS APPROPRIATE.

F. A LISTING OF THE AOC'S WILL BE MAINTAINED BY THE AOPO STAFF. A COPY WILL BE PROVIDED TO EACH AOC. FACILITIES ARE REQUIRED TO NOTIFY THE AOPO OF ANY CHANGES IN THE STATUS OF THE DESIGNATED AOC AS THEY OCCUR.

PAGE NO.	NO. OF PGS	SECURITY CLASSIFICATION
3	5	

STANDARD FORM 14
REVISED AUGUST 1967
GSA FPMR (41 CFR) 101-35.306

U.S. GOVERNMENT PRINTING OFFICE 1976 O - 207-375

14-102

CIRCULAR 10-87-8
SUPPLEMENT NO. 2
August 21, 1987

TELEGRAPHIC MESSAGE

NAME OF AGENCY

PRECEDENCE
ACTION:
INFO:

SECURITY CLASSIFICATION

ACCOUNTING CLASSIFICATION

DATE PREPARED

TYPE OF MESSAGE
☐ SINGLE
☐ BOOK
☐ MULTIPLE-ADDRESS

FOR INFORMATION CALL
NAME
PHONE NUMBER

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

G. ON A PERIODIC BASIS, THE AOC'S WILL BE PROVIDED 'MAILOUTS' (I.E., INFORMATION PACKAGES) BY THE AOPO WHICH WILL INCLUDE PERTINENT AO RELATED INFORMATION. THE AOC WILL BE RESPONSIBLE FOR DISSEMINATING/SHARING THIS INFORMATION WITH THOSE INVOLVED IN AO RELATED ACTIVITIES. THE EP (ENVIRONMENTAL PHYSICIANS) LISTING WILL CONTINUE TO BE MAINTAINED AND MAILOUTS WILL CONTINUE TO BE PROVIDED TO THE EP'S BY AOPO.

H. THIS CIRCULAR DOES NOT DIMINISH THE RESPONSIBILITIES OF THE EP'S OR DESIGNATED MAS STAFF AS SPECIFIED IN CIRCULAR 10-87-8.

I. THE AOPO HAS NEW ROUTING SYMBOLS AND TELEPHONE NUMBERS AS FOLLOWS: DIRECTOR, AOPO (10B/A0) AND AGENT ORANGE REGISTRY COORDINATOR, AOPO (10B/A01). NEW TELEPHONE NUMBERS ARE FTS 373-4118 AND COMMERCIAL (202) 233-4118.

SECURITY CLASSIFICATION

PAGE NO.	NO. OF PGS.
4	5

STANDARD FORM 14
REVISED AUGUST 1967
GSA FPMR (41 CFR) 101-35.306

U.S. GOVERNMENT PRINTING OFFICE : 1976 O-207-325

14-102

CIRCULAR 10-87-8
SUPPLEMENT NO. 2
August 21, 1987

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE ACTION INFO:	SECURITY CLASSIFICATION
ACCOUNTING CLASSIFICATION	DATE PREPARED	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☐ MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME	PHONE NUMBER	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

J. QUESTIONS CONCERNING THIS TWX CAN BE DIRECTED TO MRS. ELAINE MORROW, (10B/A01), VA CENTRAL OFFICE, FTS 373-4118.

4. REFERENCES: NONE.

5. RESCISSIONS: DM&S CIRCULAR 10-87-8 AND THIS SUPPLEMENT WILL BE RESCINDED FEBRUARY 16, 1988. THIS SUPPLEMENT WILL NOT BE CONFIRMED WITH A PRINTED ISSUE.

6. FOLLOW-UP RESPONSIBILITY: DIRECTOR, AOPO. (10B/A0).

Arthur J. Lewis MD
ARTHUR J. LEWIS, M.D.
Deputy Chief Medical Director

DISTRIBUTION: COA: (10) only
SS (10BAO) FLD: 200-2
EX: Boxes 44-6 & 88-2, Boxes 104, 60, 54, 52-1 each & 63-5

PAGE NO.	NO. OF PGS.	SECURITY CLASSIFICATION
5	5	

STANDARD FORM 14
REVISED AUGUST 1967
GSA FPMR (41 CFR) 101-35.306

U.S. GOVERNMENT PRINTING OFFICE 1976 O—207-325

14-107

Department of Medicine
and Surgery

Washington D.C. 20420

Veterans
Administration

JUL . 1987

In Reply Refer To: 136F

Mr. Thomas A. Sherwood
Director, Health Policy and Planning
Vietnam Veterans of America, Inc.
2001 S Street, N.W., Suite 700
Washington, D.C. 20009-1125

Dear Mr. Sherwood:

This letter is in response to the inquiry you addressed to Mr. Michael M. Lawson, Director, Medical Administration Service (MAS) regarding how medical centers count visits made by veterans whose patient data cards indicate a claim of exposure to Agent Orange.

On July 13, 1987, Karen Walters, Chief, Policies and Procedures Division, MAS (136F), discussed the problem with you and explained the data that is included in the outpatient file maintained by the Austin Data Processing Center and the dispositioning of visits that are included in the Agent Orange special survey. This issue was discussed on a national conference call held on Wednesday, July 15, 1987, for all Chiefs of MAS at medical centers and outpatient clinics. Specifically, Chiefs were requested to review procedures for collecting special survey information with their clerks and to remind them that a code on the patient data card for Agent Orange exposure is not to be used to disposition visits in the survey.

Thank you for bringing this problem to our attention so that it could be corrected.

Sincerely,

R. E. LINDSEY, JR.
Director for Operations

Vietnam Veterans of America Inc
2001 S St. NW
Suite 700
Washington, DC 20009-1125

(202) 332-2700

TO: Michael Lawson, Director MAS VACO

THRU: Dr. Arthur J. Lewis, Deputy CMD

THRU: David B. Van Hooser, Director Medical Information
Resources Management, VACO

Dear Mr. Lawson:

It has come to our attention that in different Medical Centers the ambulatory visit of veterans with Agent Orange (A/O) stamped on their authorizing purple cards are counted in different ways, for example:

- A closed A/O case is logged as an A/O visit even if they don't have an A/O complaint.
- A closed A/O case is logged as a regular ambulatory visit even if the visit concerns chloracne.
- An open A/O case is logged as a regular ambulatory visit when the visit relates to presumptive A/O treatment.
- An open A/O case is logged as an A/O visit.

Our information indicates that every possibility and variation on the above and other possibilities as well now occurs throughout the Medical Centers (and even within the same Medical Center) on this subject. Also, inspite of the existence of Circular 10-87-8 on A/O, numerous training programs and tapes (which are all necessary and appreciated) on A/O, there appears to be no organized centrally directed set of instructions or strategy which would prevent the above confusion from occuring.

The adverse consequences of the lack of accurate reporting are probably many but there are at least two concerns we have, namely, the integrity of the data base in terms of the total number of A/O visits reported at the end of any given fiscal year, and the dilution factor associated with the logging of all visits of veterans with A/O marked authorization purple cards as A/O visits when they are not in some cases. Needless, to say in the latter case if all patient complaints are charged to A/O visits, the possible correlation between any specific sign or symptom and A/O could be severely weakened away from statistical significance.

Our request is that at the very least an organized centrally directed rational system of ambulatory visits be employed throughout the system in a standardized manner so that everyone is clear what and which are A/O visits and non A/O visits as well as why and how exactly their visits are accordingly documented.

Sincerely,

Thomas A. Sherwood
Director, Health Policy and Planning
Vietnam Veterans of America, Inc.

Mary Stout

National Secretary
Vietnam Veterans of America, Inc.

E. R. ZUMWALT, JR.
ADMIRAL, U. S. NAVY (RET.)

8 June 1988

The Honorable Alan Cranston
United States Senate
Committee on Veterans' Affairs
Washington, D.C. 20510-6375

Dear Senator Cranston:

Attached are my answers to the questions you sent to me in your letter of June 2, 1988. I would be grateful if you would read my "Additional Comment."

All best wishes.

Sincerely,

E. R. Zumwalt, Jr.

1500 Wilson Boulevard
Arlington, Virginia 22209
703/841-8960

Attachment

Dr. Arnold Schecter (88 Aldrich Avenue, Binghamton, New York 13903) who has taken samples of dioxin from Vietnamese in South Vietnam has found elevated levels of dioxin in their bodies; whereas the dioxin levels he has taken from Vietnamese in the North (where Agent Orange was not used) are normal.

These people in South Vietnam who have continued to live in Agent Orange sprayed areas would understandably be expected to have greater readings than Americans who have been away from Agent Orange for years and whose bodies have gradually eliminated the majority of their elevated levels of dioxin.

Additional Comment

I repeat what I said during my appearance before the Committee. I am shocked by the blatantly flawed testimony of those witnesses who came for you who have disregarded the data from the Kansas University/NCI study of the Kansas farmers who used 2,4-D (where six to eight times as many compared to the control group came down with non-Hodgkins lymphoma), the study on the use of 2,4,5-T in Oregon where birth deformaties and defects increased by three-fold, and the comparison of Marines who served in Vietnam with those who did not which showed 110% more lymphomas among the Vietnam veterans and 57% more lung cancer.

Follow-up Answers for May 12, 1988, Hearing on Agent Orange Legislation and Oversight Issues from Admiral E. R. Zumwalt, Jr. to Senator Alan Cranston, Chairman

1. The Office of Technology Assessment (OTA), in discussing the blood validation work carried out for the Centers for Disease Control (CDC) Agent Orange Study, stated in its written testimony (page 2) for the May 12 hearing that "[i]t appears, therefore, that direct exposure during or shortly after ranch hand spraying would have been relatively rare among ground troops. . . ." Is is correct that the Ranch Hand spraying missions generally attempted to avoid spraying areas when U.S. military personnel were present?

I do not believe that the coordination between Ranch Hand sprayers and airmen, Marines, soldiers and sailors on the ground or in the waters of Vietnam existed. As the Commander who had responsibility, I can state flatly that there was no way in which the daily locations of my individual sailors could have been known to Ranch Hand sprayers. I believe that also to be the case for the other services.

Moreover, the exposure to Agent Orange would, in any event, have existed as those on the ground and in the waters ate the native food, drank the local water, and bathed in local waterways.

2. The OTA went on to note (page 4) that "[b]ased on current evidence, it appears that few ground troops have elevated levels of dioxin in their bodies. The group troops tested [by the CDC] may not be representative of all ground troops, but CDC, in its validation study, did attempt to identify men in highly-sprayed areas who had the greatest potential for exposure. . . ." Based on your personal experiences in Vietnam, what is your reaction to these statements?

In my judgment, government authorities have gone to great lengths to avoid assembling all the data about dioxin levels.

WRITTEN QUESTIONS FROM SENATOR DASCHLE TO THE AGENT ORANGE WORKING GROUP AND THE RESPONSES

Supplemental Questions from Senator Daschle as contained in Senator Cranston's June 6, 1988 letter.

Question #1 The nature of the relationship between Agent Orange and disease is of crucial importance for understanding the debate about Agent Orange compensation. For the record, I would like your opinion on this issue to be clear. In the testimony you submitted to the Committee, you wrote: "...in the studies which have come to conclusion, we are seeing no cause-effect relationship between service in Vietnam and possible exposure to Agent Orange and adverse health." Are you suggesting that dioxin can be exonerated as a causative agent in human illness? Are you saying that we don't need more studies?

Answer We are not suggesting that dioxin can be exonerated as a causative agent in human illness. We are only saying that to date we are seeing no cause-effect relationship. The biggest obstacle being the Agent Orange exposure assessment. However, this obstacle is being hurdled in both the Ranch Hand and NIOSH Production Worker Study where TCDD serum analysis is being utilized as the exposure assessment. These two studies will directly address this issue of the cause-effect relationship. However, the just completed Vietnam Experience Study would appear to show that ground troops have no major health problems other than those related to stress. In response to your question concerning more studies, we don't need to design additional studies at this time; but we do need to await the results of the ongoing studies mentioned above as well as CDC's Selected Cancers Study which should be completed in early 1990.

Question #2 To evaluate the existence of a cause and effect relationship between a chemical and the incidence of disease, one would look for a dose-response relationship. Such an analysis requires some measure of "dose," or, in this case, extent of exposure to Agent Orange. Isn't it true, however, that no study yet concluded has an accurate Agent Orange exposure estimate?

Answer The dose or extent of exposure are well addressed in our testimony of May 12, 1988 before the Senate Committee. As Dr. James Mason, Director of the Centers for Disease Control who testified with me stated, "specific problems or lack thereof associated with Agent Orange experience, needs to await the findings of the Air Force Health Study, and the National Institute of Occupational Safety and Health (NIOSH) Production Worker Study. In both these studies, exposure will be determined by serum values of TCDD measured by CDC".

Question #3 Why are minutes of the Ranch Hand Peer Review Group meetings routed through the Agent Orange Working Group, when the Ranch Hand study protocol states that the flow of data analysis is to go directly between the Air Force scientists and the Peer Review Group?

Answer Copies of the minutes of the Advisory Committee, chaired by Dr. Robert Miller of the National Cancer Institute (NCI) are provided to the DPC/AOWG as a courtesy and are not "routed through" me as Chairman. The flow between the Advisory Committee and the Air Force Scientists is not impeded in any way.

Results of action or inaction following such peer review by the Advisory Committee, are reported to the Secretary of the U.S. Department of Health and Human Services as is required.

WRITTEN QUESTIONS FROM SENATOR DASCHLE TO DR. RICHARD ALBANESE AND THE RESPONSES

Question 1: In your answer to a question at the hearing concerning your motivation for writing the 1988 report, you responded that you wanted to make clear that the Ranch Hand results were inconclusive; Agent Orange could not be exonerated, nor could it be proved to be a cause of disease. Your scientific objectivity may confuse some observers. I'd like to ask you a question, and request a yes or no answer. Is it fair to say that dioxin may be actively causing ill health among Ranch Handers?

Answer 1: Yes, in my opinion, it is fair to say that dioxin may be actively causing ill health among Ranch Handers.

Question 2: The Ranch Hand Advisory Committee/Peer Review Group recommended changes to the conclusions of the original 1984 Ranch Hand report, which had the effect of deemphasizing the evidence linking dioxin exposure to health disorders in the Ranch Hand population. The same Advisory Group recommended withholding the December 1984 report on birth defects in the Ranch Hand population. In addition, the Advisory Group recommended revisions of the February 1988 report. In your view, why has the Advisory Group taken these actions?

Answer 2: I do not fully concur with the three recommendation of the Ranch Hand Advisory Committee that you have mentioned. I do not understand the Advisory groups recommendations in terms of scientific data and methodology. I believe the Advisory Committee recommendations were influenced by its composition which is not in accord with the specifications of the study protocol. Particularly the protocol requires that the Advisory Committee contain scientifi members nominated by veterans advocacy groups. To my knowledge, such members were not present on the Advisory Committee, and, in my opinion, their absence has had the effect that an important point o view has been incompletely represented.

In an epidemiological study, through the choice of critical levels in statistical testing and other aspects of data interpretation, the researcher influences the risk or probability that the taxpayer will be incorrectly or unjustly required to pay for an injury not caused by government action, and the researcher influences the risk or probability that society will fail to care for an individual who has been hurt by a government action. Different researchers weigh these two risks differently because of individual, personal values.

It is because of the subjective, value-laden aspects of public health work that it is recommended that advisory groups be composed so that all interests are represented. The need to have all constituencies represented seems clearly articulated by Dr. Kotin i his 1979 Supplanting Memorial Lecture published in the Journal of Occupational Medicine. Further, the research of Professor Nicholas Steneck at the University of Michigan, Collegiate Institute for Values and Science, demonstrates through detailed case studies, the intimate interaction or science and values in public health issues, and the great importance of balanced representation on standard setting panels (reference: N.H. Steneck. The Microwave Debate. The M.I.T. Press 1984; N.H. Steneck. "Subjectivity in Standards:

The Case of ANSI C95.1-1982." Microwaves & RF, May 1983, page 137.

The Ranch Hand study protocol, understanding the importance of constituency representation, required scientific personnel nominate by veterans advocacy groups to be members of the Advisory Group. T my knowledge, this representation has not occurred.

Question 3: The Ranch Hand study protocol, which was written carefully to protect the integrity of the study, requires that the Advisory Group contain "approximately equal representation...betwee government scientists, academic scientists, and scientific personne nominated by veterans advocacy groups." To your knowledge, did the Advisory Group meet this protocol requirement? If not, please explain.

Answer 3: To my knowledge, the Advisory Group did not meet th protocol requirement that the group contain scientific personnel nominated by veterans advocacy groups. I cannot explain this departure.

Question 4: Are you aware of other departures from the Ranch Hand study protocol?

Answer 4: In my opinion, Air Force scientists have been fastidious and expert in their adherence to the protocol. I believ that a peer review group augmented by an appropriate number of scientists nominated by veterans groups would improve interpretatio of data in the Ranch Hand and other governmental studies.

EPA'S RESPONSES TO FOLLOW-UP QUESTIONS FOR MAY 12, 1988 HEARING ON AGENT ORANGE-RELATED ISSUES FROM SENATOR DASCHLE

Question 1

"Is the EPA currently in the process of revising its valuation of the toxicity of dioxin?"

Response to Question 1

The Agency is completing a reassessment of the carcinogenicity of 2,3,7,8-TCDD, which updates an earlier assessment issued in 1985. The reassessment will be made available in June for a period of public comment, after which the Agency's Science Advisory Board will conduct a peer-review this fall.

Question 2

"On what basis does the EPA assess the health effects of a substance such as dioxin? Does the health assessment group consider studies of animals as well as humans?"

Response to Question 2

The Agency examines the full range of known toxic effects of compounds during its assessment phase.

While adequate human data are clearly preferrable (if available) when estimating human risks, the Agency considers all available information, including animal data -- which in many cases form the primary basis for the assessment, due to limitations in or absence of information in humans.

Question 3

"The September 1985 Health Assessment Document includes a bibliography of over several hundred studies. Were many of those animal studies? Isn't it true that the EPA bases its assessment of the cancer-causing potential of dioxin by reviewing studies of animals and humans?"

Response to Question 3

Not all of the studies cited in the 1985 document dealt with toxicity. Some of them deal with physical and chemical properties, which is useful information in trying to understand how the chemical behaves in the environment. However, of the toxicological papers cited in the document, the vast majority of them were animal or _in vitro_ ("test tube") studies, rather than human studies. This is consistent with a preponderance of non-human studies in the general scientific literature on 2,3,7,8-TCDD.

In reaching its risk assessment decision, the Agency evaluates all of the available scientific data, including both human and non-human data.

Question 4

"What is the current status of dioxin in relation to cancer?"

Response to Question 4

The current position of EPA on 2,3,7,8-TCDD is found in the 1985 Health Assessment Document.

Specifically, in the view of EPA, there is sufficient evidence to conclude that 2,3,7,8-TCDD is carcinogenic in rats and mice who are exposed throughout the major part of their lifetimes. However, there is insufficient evidence to reach a conclusion about the demonstrable carcinogenicity of 2,3,7,8-TCDD in humans.

This view is summarized in assigning 2,3,7,8-TCDD to the "B2" category in the Agency's weight-of-the-evidence scheme (See EPA's Guidelines for Carcinogen Risk Assessment, Federal Register, Vol. 51, No. 185, September 24, 1986, pp 33992-34003). This category is designated as "probable human carcinogens," although as it appears here, the word "probable" is a term-of-art. This view is essentially the same as that taken by the International Agency for Research on Cancer (IARC).

In addition, the 1985 EPA document calculates an estimated potency for 2,3,7,8-TCDD of 1.6 x 10**5 (mg/kg-d)-1.

The Agency is currently completing a reassessment of its 1985 position on the carcinogenicity of 2,3,7,8-TCDD which will be distributed for public comment later this month. Those comments will be available for a Science Advisory Board meeting to discuss the reasessment this fall.

Question 5

"Is dioxin still considered to be a cancer causing agent? Is dioxin a cancer promoting agent?"

Response to Question 5

The fact that administration of 2,3,7,8-TCDD can lead to cancer in laboratory animals is not debated in the scientific community. The detailed mechanism by which 2,3,7,8-TCDD leads to cancer in experimental animals, however, remains unknown. It is known that the chemical has certain properties of a promoting agent, based on positive responses in assays designed to detect promoting action. The extent to which the capacity of 2,3,7,8-TCDD to induce cancers in laboratory animals is due solely to its promoting capability is unknown and is the subject of discussion both inside and outside the Agency.

Question 6

"Isn't it true that dioxin is still number one on the EPA's list of carcinogens?"

Response to Question 6

The answer to this question is related to what one means by being "number one." I will address the question from three points of view:

a. If one is concerned about human carcinogens, it should be noted that there are roughly 26 chemicals and mixtures of chemicals which are known to cause cancer in humans. 2,3,7,8-TCDD is not one of them. Therefore, in this sense there are chemicals "higher on the list" (of greater concern) than 2,3,7,8-TCDD.

b. If one is concerned about animal carcinogens, it should be noted that 2,3,7,8-TCDD is the most potent chemical reviewed by the Agency in its ability to generate tumors in animals to which it is administered. That is, in comparison to other chemicals, it takes less 2,3,7,8-TCDD to generate cancer in animals than any other chemical tested to date. In this sense, the chemical "goes to the top of the list."

c. Generally, the Agency is concerned about the risk posed by various chemicals in the environment. The concept of risk includes both the potency of the chemical and the exposure to that chemical. Exposure, in turn, depends about such things as the amount of the chemical in the environment, the concentrations at which it is found, the media in which it is found, the proximity to humans, the number of humans exposed, etc. There are other substances and situations; e.g., radon in homes, that rank higher on this list of risks than does 2,3,7,8-TCDD in the environment.

Question 7

"You testified that biological factors affect the movement and storage of dioxin in the body. Could you explain how this fact affects half-life estimates and the reliability of an exposure measure based on blood tests?"

Response to Question 7

The detailed mechanism by which 2,3,7,8-TCDD is absorbed, distributed, metabolized and eliminated from humans is not well-known. More detailed studies have been conducted in animals; and, while much has been learned, much more remains to be learned.

The estimates of the half-life of 2,3,7,8-TCDD in humans have resulted from a number of different studies, using different subjects, exposed in different ways. Some studies have looked at levels of 2,3,7,8-TCDD in veterans, examined several years after their last exposure. Similar studies have been conducted on workers who were exposed in occupational and industrial accident situations. One study has even followed the half-life of radioactive 2,3,7,8-TCDD ingested by a researcher in another country. All of these studies have limitations, but the general conclusion is the same: The half-life of 2,3,7,8-TCDD in human fatty tissue is on the order of years (probably 5-10 yrs), rather than the weeks to months observed in most laboratory animals or the one year reported in monkeys.

The reason for this wide variation is not known. The significance of the magnitude of the half-life is also open to question. Some have argued that the long half-life in fatty tissue makes the human "at risk" for a longer period of time. Others have argued that long-term storage in the fatty tissues actually "sequesters" the chemical, limiting its ability to elicit a toxic reaction.

The blood tests conducted by the Centers for Disease Control (CDC) have provided a relatively non-invasive method for estimating the concentration of 2,3,7,8-TCDD in the fatty tissues of the body. These results, like those of earlier studies of similar compounds (cf., PCBs) show that the concentration of the chemical in the fat seems to be independent of the source of the fat; i.e., whether it comes from adipose tissue, the blood, or human milk. Based studies at CDC and other laboratories, it appears that the residual level of 2,3,7,8-TCDD in the fatty tissues of the body is probably pretty good indicator of previous exposures to 2,3,7,8-TCDD. However, this assumes that different human bodies deal with 2,3,7,8-TCDD in the same way. Some researchers have questioned the applicability of this assumption.

Full resolution of these issues will have to await additional research.

VETERANS ADMINISTRATION
1930

The Deputy Administrator
of Veterans Affairs
Washington, D.C. 20420

JUL 18 1988

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find my response to the question which you forwarded on behalf of Senator Tom Daschle for the May 12, 1988, hearing by the Senate Veterans' Affairs Committee. Thank you for the opportunity to provide this additional information for the record.

Sincerely,

Thomas E. Harvey

THOMAS E. HARVEY
Deputy Administrator

Enclosure

cc: Honorable Frank H. Murkowski
Honorable Thomas A. Daschle

QUESTION FOR THOMAS E. HARVEY, DEPUTY ADMINISTRATOR OF VETERANS AFFAIRS
SUBMITTED BY SENATOR TOM DASCHLE

QUESTION: In referring to compensation for health damage related to Agent Orange exposure, you testified, and I think I am quoting you correctly, that "this sop will not keep Vietnam veterans quiet." Why would you characterize legislation which would provide significant benefits to many Vietnam veterans as a "sop"?

ANSWER: I don't recall making such statement during the May 12, 1988 hearing, and didn't notice the use of that phrase in reviewing the transcript of that hearing. But let me take the opportunity to adopt the phrase as my own.

The dictionary defines "sop" as "something given to pacify or quiet..." Legislation providing monetary benefits to veterans in response to the clamor of a few -- rather than in response to credible scientific evidence -- is a sop. And it won't keep Vietnam veterans with other illnesses which are not being compensated -- and also are not related to Agent Orange exposure by credible scientific evidence -- from continuing the clamor.

The Veterans Administration disability compensation system is predicated upon the concept of compensating veterans for injuries or illness incurred in or aggravated by military service. Where that concept of "incurred in or aggravated by" is lacking, the provision of monetary compensation is really no more than a give-away. And if one is to begin providing such compensation to veterans for particular illnesses without the establishment of a causal relationship to military service, why not provide such compensation for any and all other illnesses those veterans may suffer.

Passage of legislation that would presume service connection for certain diseases that is not based upon sound scientific evidence would be a disservice to Vietnam veterans. It would be a disservice because it would perpetuate the erroneous perception that Agent Orange is responsible for a whole host of maladies. That is simply not true. It would be a disservice because it would call into further question the integrity of the Veterans Administration's compensation system. The more diseases are added to the presumptive compensation list where scientific basis is lacking, the less defensible that system becomes. And finally, it would be a disservice because it ignores the quality scientific research that has been carried out by the Federal government on behalf of Vietnam veterans.

Vietnam veterans are entitled to the truth about Agent Orange. We have been pursuing all avenues to learn the truth. Legislation based on emotion -- rather than on credible scientific evidence -- falls far short of that responsibility. As I said in my testimony it is bad public policy and bad science.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

JUN 28 1988

The Honorable Alan Cranston
Chairman, Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in response to your June 6 letter requesting answers to questions submitted by Senator Tom Daschle in follow up to the May 12, 1988, hearing on Agent Orange-related issues.

Enclosed are our responses to Senator Daschle's questions.

Sincerely yours,

James O. Mason

James O. Mason, M.D., Dr.P.H.
Assistant Surgeon General
Director

Enclosure

Questions for Dr. James O. Mason, Centers for Disease Control,
Submitted by Senator Tom Daschle in Follow Up to
May 12 Hearing on Agent Orange

1. Question:

In your testimony for the Committee, you noted that there are "several suggestive studies" with respect to a possible causal link between dioxin and non-Hodgkin's lymphoma. Do "several suggestive studies" constitute the "reasonable doubt" described in PL 98-542? If not, what would constitute reasonable doubt?

Answer:

The determination of the "reasonable doubt" described in PL 98-542 is the responsibility of the Veterans Administration and the Congress. The epidemiologic studies of the health of Vietnam Veterans is the responsibility of CDC and does provide information to the VA and Congress on which to make policy decisions.

2. Question:

Referring to the Vietnam Experience Study (VES), you testified that CDC investigators found a higher incidence of non-Hodgkin's lymphomas in Vietnam veterans than in non-Vietnam veterans. You noted that the numbers were, in both cases, very small, with six reported cases among Vietnam veterans and one among non-Vietnam veterans. In your written testimony, you claimed that "these numbers are too few for drawing conclusions."

(A) Question:

Why did you not report measures of statistical significance for this finding?

Answer:

In our May 20 letter to Senators Cranston and Murkowski, we updated the information provided in our testimony. We now report seven confirmed cases of non-Hodgkin's lymphoma among Vietnam veterans.

We did not report measures of statistical significance because we believe the numbers of specific types of cancer are too few for drawing conclusions. Statistical testing can be performed, and the difference between these numbers is statistically significant ($p = .04$). There are, however, a number of caveats pertinent to the report of these crude results. First, the non-Hodgkin's lymphoma cases are not homogeneous in regard to cell type. Two of the Vietnam veterans had Burkitt's lymphoma, a type of lymphoma which is often categorized separately from other non-Hodgkin's lymphomas. Second, the crude analysis does not consider the time of diagnosis. One of the Vietnam veterans was diagnosed with non-Hodgkin's lymphoma while serving in Vietnam. Two of the other veterans were diagnosed within 3 and 4 years after leaving Vietnam. Since environmentally related cancers usually exhibit a longer latent period than observed in these veterans, it is questionable whether these early cases are related to an exposure which occurred in the service.

(B) Question:

How many non-Hodgkin's lymphomas should have been expected in the two groups of veterans?

Answer:

Based on average annual age-specific U.S. incidence rates reported by the National Cancer Institute (SEER 1973-1977), 3.9 cases of non-Hodgkin's lymphoma would be expected among Vietnam veterans and 3.5 cases would be expected among non-Vietnam veterans. A comparison between these "expected" numbers and our results assumes that case ascertainment was similar in SEER and VES. Given the methodologic differences between SEER and VES, this assumption may not be valid.

(C) Question:

Why does the VES report in the Journal of the American Medical Association omit any mention of the non-Hodgkin's lymphomas?

Answer:

As stated in the 1983 original study protocol, the Vietnam Experience Study (VES) would not identify enough cases of individual types of cancer to evaluate Vietnam veterans' risks for specific cancers. That is why CDC designed and is conducting the Selected Cancers Study. Also, the original design of the VES did not include the verification of cancers reported by veterans during the telephone interview. Accordingly, in presenting the major findings from the VES in JAMA, we only presented data on reported cancers as a group.

Our report of the total number of confirmed (based on a review of medical records) non-Hodgkin's lymphomas among Vietnam and non-Vietnam veterans in the VES is the result of an additional substudy not included in the initial protocol. The ascertainment of medical records and analyses of these data were not completed at the time the JAMA articles were written.

(D) Question:

Your testimony indicates that four of the total of seven non-Hodgkin's lymphomas have been confirmed. Do you plan to confirm the remainder of the cancers? Is the VES finished, or do you plan to follow up on this and other findings still under investigation?

Answer:

All cases of non-Hodgkin's lymphoma from the VES have now been confirmed. As reported in our May 20 letter to Senators Cranston and Murkowski, there were seven confirmed cases in the Vietnam group and one confirmed case in the non-Vietnam group.

The VES is basically finished except, as proposed in the original protocol, for possible mortality updates of these cohorts.

3. Question:

Critics of the government's handling of the Agent Orange issue have claimed that the government emphasizes scientific findings which support its stated position that Agent Orange has not been shown to be a cause of health problems for Vietnam veterans, and deemphasizes those that suggest the opposite. For example, the report on the Vietnam Experience Study cites large differences in cerebrospinal malformations (CSM) between Vietnam and non-Vietnam veterans. Vietnam veterans had 26 confirmed cases of CSM, compared to 12 confirmed cases among non-Vietnam veterans. The findings are reported in a table of "observed" vs. "expected" malformations, the report concludes that the Vietnam veteran findings are in the "expected" range, and the non-Vietnam veteran findings are the result of the underreporting by men in that group.

(A) Question:

Why were the CSM findings reported using observed vs. expected numbers, rather than reporting the statistical significance of the group differences between Vietnam and non-Vietnam veterans? The latter approach seems to be most frequently used in the VES, as well as other studies (including those conducted by the CDC), in comparing two groups of veterans.

Answer:

The Cerebrospinal Malformation (CSM) Study was fundamentally different in its design and approach than other components of the VES. In all other components, cohorts of Vietnam and non-Vietnam veterans (or their children) were selected through a sampling procedure, and health outcomes were ascertained for all members of each sample. In contrast, in the CSM Study, we attempted to verify reported positive cases. These positive cases were chosen for verification because of their fathers' reports during the interview; they were not members of a random or representative sample. No attempt was made to validate negative responses (i.e., children with no reported CSM) because these defects are very rare. A study that relies on verification of positive reports will yield valid estimates of risk only if all true cases are reported. It will not yield valid estimates of risk if CSM's were differentially reported by the two cohorts in the interview or if our ability to verify the reported cases differed by cohort.

We had evidence to support the possibility of differential reporting in the interview. First, in the stillbirth series, which was independent of veterans' reports of birth defects, the number of CSM cases was very similar in the two cohorts (five cases among children of Vietnam veterans, six cases among children of non-Vietnam veterans). (All children reported as stillborn were included in the CSM Study, regardless of their fathers' reports about the presence or absence of birth defects.) Second, the total number of records-based CSM's in the non-Vietnam cohort was much lower than would be expected in a population this size. This certainly suggests the possibility that we did not find all the cases in the non-Vietnam cohort.

In addition to the possibility of differential reporting in the interview, our ability to verify the reported cases differed by cohort; records were obtained for 82.5% of the eligible children of Vietnam veterans, and for only 67.1% of the eligible children of non-Vietnam veterans. This difference was due almost entirely to the fact that non-Vietnam veterans refused to participate more often than Vietnam veterans. As a result, we had less of an opportunity to verify cases in the non-Vietnam cohort because we were able to obtain a smaller percentage of their records.

Under these circumstances, i.e., no validation of reported negatives, evidence of underreporting in one cohort, and differential participation in the study, we believe that it is inappropriate to calculate rates or measures of differential risk because such measures may be invalid. Consequently, we chose to present our results as observed numbers of cases in each cohort, and to present the expected numbers as a comparison for the reader.

(B) Question:

How would you respond to the suggestion that the CDC is "scrubbing" the findings to emphasize results consistent with earlier reported conclusions, and deemphasizing inconsistent results?

Answer:

We used our best scientific judgment in deciding the manner of presentation of the CSM data. We believe that to have presented the data in any other way would have been misleading and an overinterpretation of data derived from a weak study design.

In the JAMA article, we did not conclude that there were no differences between the cohorts. We stated "these data may reflect true differences between the cohorts, or may be due to differences in the opportunity to identify and verify CSM cases" and that "there is evidence to suggest the latter." We believe that this reflects a responsible and thoughtful approach to the data. Our design, results, and presentation of this study were peer reviewed on a regular basis by the Institute of Medicine, and the JAMA articles were reviewed by the Office of Technology Assessment and the JAMA reviewers prior to publication.

4. Question:

The Centers for Disease Control has found that an Agent Orange study cannot be done. Others in the scientific community, including the Office of Technology Assessment and the Agent Orange Working Group, agree. Yet the reason a study is infeasible is that we cannot determine an exposure estimate. Therefore, how can we say there is no association between Agent Orange and disease when we don't even know who was exposed or how much exposure they received?

Answer:

As stated in our May 12 testimony, CDC has said that "specific problems or lack thereof associated with Agent Orange exposure need to await the findings of the Air Force Health Study and the National Institute for Occupational Safety and Health Production Worker Study." In both of these studies, exposure will be determined by serum values of TCDD measured by CDC.

Office of General Counsel Washington D.C. 20420

Veterans Administration

July 6, 1988

In Reply Refer To:

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find my responses to the questions which you forwarded on behalf of Senator Tom Daschle for the May 12, 1988, hearing regarding Agent Orange related issues. Thank you for the opportunity to provide this additional information for the record.

Sincerely,

OLIVER MEADOWS
Chairman, Veterans' Advisory Committee
on Environmental Hazards

Enclosure

cc: Honorable Thomas A. Daschle
Honorable Frank H. Murkowski

QUESTIONS SUBMITTED BY SENATOR TOM DASCHLE
FOR MR. OLIVER MEADOWS, CHAIRMAN, VETERANS'
ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS
FOR THE MAY 12, 1988 HEARING

QUESTION 1. In your written testimony, you say that your opposition to establishing a presumption in favor of Vietnam veterans is based on the lack of conclusive scientific evidence of a causal link between disease and Agent Orange. Isn't this the same sort of logic the Senate rejected when it passed legislation compensating atomic veterans? Didn't the Environmental Hazards Group also oppose the atomic veterans compensation bill?

ANSWER: The Veterans' Advisory Committee on Environmental Hazards arrived at its conclusions following its consideration of the currently available scientific literature. It reflects the collective judgment of the members of the Scientific Council, made up of highly regarded professionals from a variety of scientific disciplines and four lay members of the Committee. The Congress of the United States, for whatever reasons, may choose to pursue a particular course of action, which may or may not be consistent with the Committee's assessment of the scientific literature.

QUESTION 2. Atomic veterans had to wait 40 years for Congress to take action. How long do you think it might take to "prove" to your satisfaction that Agent Orange is, or is not, a causal factor in the development of disease?

ANSWER: As your initial question indicates, the Committee has concluded that the scientific evidence available thus far has not demonstrated causal association between exposure to Agent Orange and the subsequent development of diseases. When, if ever, such a causal association may be established is impossible to answer. It is only possible to say that it has not been established to our satisfaction yet.

WRITTEN QUESTIONS FROM SENATOR DASCHLE TO DR. JOEL MICHALEK

AND THE RESPONSES

Question 1: This February, the Air Force released "United States Air Force Personnel and Exposure to Herbicide Orange" which reviewed the morbidity of Ranch Hand personnel in eleven clinical areas. In written testimony submitted to the Committee, the Air Force contended that the "conclusions [of the 1988 report] were essentially the same as in previous reports' The Air Force has also described the 1984 Ranch Hand study as "reassuring." Is it fair to say the birth defects information included in the 1988 report is new to the public?

Answer 1: Yes, the reported birth defect information in the 1988 report is new to the public. As I have already testified, it corrects the baseline analysis of reported birth defects by showing that the group difference seen at baseline is not restricted to minor defects of the skin, but is, in fact, independent of severity. The word "reassuring" was used in the baseline report to indicate that the Ranch Hands were not experiencing the adverse health conditions claimed as resulting from exposure to Agent Orange by veteran activists in the media. The new reported birth defect analysis of baseline data does not alter the conclusions of the baseline report or in particular, make the results less reassuring to the Ranch Hands because, as the recent CDC study shows, reported birth defect data can be biased. The baseline reported birth defect finding has motivated a medical record verification of the birth defect status of every child fathered by the Ranch Hands and their matched Comparisons. A final report of the verified birth defect analysis will be ready by August 1989.

Question 2: Do you think the 1988 report communicates more effectively than the 1984 report that dioxin has not been exonerated as a cause of health damage?

Answer 2: It is implicit in the 1984 report that dioxin has not been exonerated. The 1988 report makes the statement explicitly. In fact, dioxin can never be "exonerated" by epidemiologic studies. At best, up to limitations in statistical power and exposure estimation, epidemiological studies can only address the question as to whether occupational exposure to dioxin is harmful. Such studies cannot establish whether occupational exposure to dioxin is safe. Hence, the statement that dioxin has not been exonerated is, in logical terms, a tautology.

Question 3: Mr. Don Newman, Chairman of the Agent Orange Working Group, testified that "we are seeing no cause-effect relationship between service in Vietnam and possible exposure to Agent Orange and adverse health." To evaluate the existence of a cause and effect relationship between a chemical and the incidence of disease, one might be expected to look for a dose-response relationship. Such an analysis requires some measure of "dose" or, in this case, extent of exposure to Agent Orange. Isn't it true, however, that the Ranch Hand study does not, in its current form, have an accurate Agent Orange exposure estimate?

Answer 3: The current exposure estimate for a Ranch Hand is simply the amount of dioxin sprayed divided by the number of men available of the same rank and job as the subject Ranch Hand during his tour.

This estimate was the best that could be devised and has had wide precedent in the field of epidemiology. For example, similar exposure estimates were applied in epidemiologic studies of occupational exposure to asbestos. Since the recent application of the CDC's serum dioxin assay to 150 Ranch Hand enlisted personnel, we have discovered, for the first time, that the exposure index is uncorrelated with current dioxin body burden. This information is new and, as yet unpublished. It certainly suggests that the current exposure index is not as accurate as we had once thought.

Question 4: In your testimony before the Committee, you noted that "the absence of a good exposure measure attenuates our ability to discover dioxin's effects." Could you explain your comment more fully?

Answer 4: While the estimated exposure index was the best measure available at the time our study began, plots of the exposure index versus current dioxin body burden suggest that the exposure index has overestimated the dioxin exposure of some Ranch Hands and underestimated the dioxin exposure of other Ranch Hands. Assumptions inherent in that index could have limited its ability to detect a true association between exposure and disease. Thus, unless the true association is very strong, we may be unable to detect it with the original exposure index. In other words, as I have testified, the absence of a good index attenuates (diminishes) our ability to discover an effect of dioxin exposure.

Question 5: Much of the recent discussion of Agent Orange levels concerns the use of blood serum tests. In your estimation, what is the most reliable measure of exposure to dioxin? Would a reliable measure be based solely on blood tests, or would you include other factors, as well? In addition, please compare and evaluate the exposure measures used in the aborted CDC study of Agent Orange, the New Jersey Agent Orange Commission study, and the Air Force Ranch Hand study.

Answer 5: The blood test results offer the first opportunity to apply current dioxin body burden measurements to assess Ranch Hand exposure to dioxin. We do not currently know how best to use this information to assess exposure. There are at least two issues that must be resolved before the CDC assay can be applied to assess individual exposure; they are: (1) Is route of entry (cutaneous, ingestion, inhalation) an important determinant of serum lipid dioxin body burden? and (2) Does dioxin half-life vary significantly with age, percent body fat, metabolic rate or disease state? To address the first of these, we have begun an extensive in-house review of dioxin pharmacokinetics. The second issue is the motive for in-house development of a regression analysis of half-life. We expect to have answers to these questions within one year. If route of entry is an important determinant, assessments of exposure might be adjusted for military occupation (flying, ground), since it is currently believed that flyers received more exposure via inhalation than through the skin. If currently measurable attributes, such as weight changes, are found to influence half-life, exposure analyses will be further adjusted fo weight changes since Vietnam. Thus, the future exposure assessmen may not be based solely on the blood tests. The specifics of that exposure assessment will depend on current work in pharmacokinetic and the statistical theory of half-life estimation.

The CDC, in its aborted ground troop study, and the Air Force in its Ranch Hand study applied demographic and work history data to assess dioxin exposure. These methods have wide precedent in the field of epidemiology, having been successfully used in studies of asbestos, radiation and toxic chemical exposures. These indices were considered the best available methods for measuring dioxin exposure until the CDC began applying the serum dioxin assay to epidemiologic cohorts in 1987.

In the aborted CDC study, investigators assessed exposure in several ways, all based on data regarding troop locations and dates, Ranch Hand spray paths and dates, toxicological data regarding the decay of dioxin in sunlight and personal estimates o exposure. A "hits" model was developed in which a "hit" was defined as any occasion on which a veterans company had a recorded location within two kilometers of an area that had been sprayed with Agent Orange in the previous six days. For each veteran; a hits score was compiled by summing all of his "hits" during his tour in Vietnam.

The Air Force index was based on monthly records of gallons of herbicide sprayed and personnel records that permitted job categorization of all Ranch Hands. The index for a given Ranch Hand was simply the amount of dioxin sprayed divided by the number of men in his job category during his tour.

Both metrics depend on the "Herbs Tape" data for gallons sprayed per month. Both metrics are subject to error and it is reasonable to expect that the CDC metric would be less accurate than the Air Force metric, since troop locations were only approximately known. The Air Force metric could be inaccurate because gallons sprayed per month were not identified by base in the Herbs Tape data and this could have little relationship to the exposure of a particular Ranch Hand or even groups of Ranch Hands.

No exposure index is identified in published accounts of the New Jersey Agent Orange Commission study. Questionnaire information on approximately 2700 veterans was reviewed to identif 100 men who "seemed likely to have handled herbicides during a tou duty in Vietnam". Thus, New Jersey investigators were studying self-reports of herbicide handling and, I assume, tour dates and data of the kind available on the Herbs Tape to determine whether the tour occurred during a period of heavy spraying. Since the Ne Jersey Commission has not published a formulation of their exposur index, I have no opinion about its accuracy relative to the Air Force and CDC indices.

Question 6: The Vietnam Experience Study, conducted by the Centers for Disease Control, includes a "Reproductive Outcomes and Child Health" report. In it, the CDC notes a statistically significant difference in reported birth defects between Vietnam and non-Vietnam veterans. The differences were based on telephone interviews with the two groups of veterans. To verify the differences, the CDC conducted a substudy of a smaller group of veterans who were scheduled for medical examinations. The smaller group was not selected randomly, included less than one-sixth of those in the original study, and relied on hospital birth records only. Could you comment on the adequacy of the procedure the CDC used to verify reported birth defects in the Vietnam Experience Study?

Answer 6: It is true that the 2282 veterans selected for the hospital birth record substudy were not randomly selected from the 15,288 veterans interviewed; they were, in fact those who participated in both the interview and the physical and who were examined after January 1, 1986. Detailed analyses of the examined veterans relative to the telephone interview participants did not show different demographic characteristics or health histories. In addition, participation in the substudy was high in both the Vietnam and non-Vietnam cohorts, and, moreover, the two cohorts were similar with respect to various demographic and military covariates. Thus there was no evidence of selection bias or participation bias in the substudy. Regarding the use of hospital birth records, as opposed to all medical records up to the age of 18, the purpose of the CDC birth defect verification was only to validate the reported birth defect rates derived from the questionnaire. The CDC investigators believed, as I do, that hospital birth records would suffice for that purpose. Additionally, hospital birth records are less subject to verification bias, a phenomenon wherein Vietnam veterans may be more sensitive than non-Vietnam veterans to the birth defect status of their children and so be more inclined to have them seen at medical facilities where defects would be discovered and reported. Thus, even if Vietnam and non-Vietnam Veterans had identical birth defect rates in their offspring, Vietnam veterans children would appear to have more verifiable defects than children of non-Vietnam veterans if this bias were operating. This is a potential bias that we will face in the currently evolving Ranch Hand birth defect verification, which considers hospital birth records and medical records up to the age of 18. Finally, I believe that CDC restricted their verification to hospital birth records because a wider search, of the kind we are doing, would have taken years to complete. In summary, I believe the CDC's use of hospital birth defect records was appropriate for their purpose and that the non-random selection of fathers for the verification substudy did not bias their results.

Question 7: During her testimony to the Committee, Hellen Gelband of the Office of Technology Assessment commented that there were no immune differences between the Ranch Hand population and the control group in the Ranch Hand findings. Is this true? Please include an explanation of the adjusted analyses in your answer.

Answer 7: Unadjusted and adjusted Ranch Hand versus Comparison contrasts were performed on seven cell surface markers and four functional stimulation variables. The results are summarized in Table 1.

Table 1
Statistical contrasts of
Ranch Hands versus Comparisons on Immunological Variables

Cell surface markers	Unadjusted	Adjusted
Total T cells (T11)	NS	****
Helper T cells (T4)	NS	NS
Suppressor T cells (T8)	NS	NS
B cells	NS	****
Monocytes	NS	****
HLA-DR cells	NS	****
T4/T8 ratio	NS	NS
Functional Stimulation		
Unstimulated response (PHA)	NS	NS
PHA net response	NS	NS
Pokeweed net response	NS	NS
MLC net response	NS	****

In Table 1, NS indicates a non significant group mean difference and **** indicates the presence of a statistically significant group by covariate interaction. A group by covariate interaction occurs when the Ranch Hand versus Comparison mean difference changes with the values of a covariate. The interactions indicated in the table are summarized in Table 2.

Table 2
Immunology Interaction Summary

Variable	Interaction
Total T cells	Group by race
B cells	Group by smoking history among non-Blacks
Monocytes	Group by occupation
	Group by current alcohol consumption
	Group by current alcohol consumption
MLC net response	Group by pack-year

Overall, no discernible pattern was identified in these interactions to suggest a detriment in any subgroup of either Ranch Hands or Comparisons.

Additionally, exposure index analyses of cell surface markers revealed no pattern consistent with a dose response relationship. For enlisted ground crew, the mean total T cell and suppressor T cell counts for the medium exposure level were significantly lower than those of the low exposure level, but were slightly lower than those of the high exposure level. The exposure index analysis of the functional stimulation tests revealed no consistent significant doseresponse patterns for net PHA counts or net MLC counts. For net pokeweed counts, enlisted flyers in the high exposure level had a significantly lower adjusted count than enlisted flyers in the low exposure level, and a decreasing trend with exposure was apparent.

In summary, Air Force investigators concluded that no significant group differences were present for the cell surface marker or functional stimulation studies and that there was no indication of impaired immunologic competence in either group. Hellen Gelband therefore agrees with the Air Force interpretation of these data.

Question 8: Major Jack Spey of the Ranch Hand Vietnam Association asserted that the Ranch Hand ground crew were more heavily exposed than the enlisted flyers. I know some ground crew members were tested in your blood tests, and I know the Air Force plans to test all Ranch Hand study participants, but I am unaware of tests already done on the enlisted flyers. Have the serum dioxin levels of the enlisted flyers or the pilots been tested? If so, please describe your findings.

Answer 8: Of the 150 Ranch Hand enlisted personnel who participated in the 1987 pilot dioxin study, recently reported in the MMWR, 19 were flying enlisted and 131 were enlisted ground personnel. The mean dioxin body burden among the flying enlisted was 22.7 ppt (parts per trillion) and the mean dioxin body burden for enlisted ground crew is 53.3 ppt. This breakout by occupation, flying versus ground, was not presented in the MMWR paper; it is currently under investigation. These data suggest that Major Jack Spey was correct in his assumption that enlisted ground personnel were more heavily exposed than enlisted flying personnel.

Question 9: Dr Barnes from the VA's Advisory Committee on Environmental Hazards testified that biological factors affect the movement and storage of dioxin in the body. Is this true? If so, could you explain how this fact affects half-life estimates and the reliability of an exposure measure based on blood tests?

Answer 9: It is true that, in theory, biological factors, such as weight changes and disease states, affect the movement and storage of dioxin in the body. We will take these factors into account with adjusted half-life estimates before applying the dioxin assay results to exposure estimation in the Ranch Hand cohort. The development of the statistical theory of adjusted half-life estimation is currently under way at the USAF School of Aerospace Medicine.

WRITTEN QUESTIONS FROM SENATOR DASCHLE TO THE OFFICE OF TECHNOLOGY ASSESSMENT AND THE RESPONSES

1. The OTA has played an important role in reviewing Agent Orange research thus far, particularly with respect to the adequacy of various approaches and methodologies for studying this problem. In your estimation, how long will it take before we have definitive scientific answers about the toxicity of Agent Orange, or of dioxin? How many years will pass before science will be able to answer this question?

2. Is there a better way to approach this problem? Given the difficulty in doing human experimentation on a substance which may be as toxic as dioxin, and the limitations involved in extrapolating from animal studies, are there any other ways to arrive at an answer?

3. You testified that the exposure measure used in the Washington study was "several-fold worse" than the current exposure measure used in the Ranch Hand Study. Could you compare the exposure measures of the Kansas farmer study and the CDC's aborted Agent Orange Exposure Study to the current Ranch Hand exposure index?

4. A member of the VA's Advisory Committee on Environmental Hazards testified that he would like to use the CDC validation study to conclude that ground troops don't have high exposures. You testified that ground troops in the blood validation study may not be representative of all ground troops. There are increasing reports that Agent Orange use may have gone far beyond the aerial Ranch Hand sprayings. For example, it has been suggested that substantial amounts of Agent Orange were sprayed via Army helicopters and Marine backpacks and around base perimeters. If it is true that Agent Orange use went far beyond previous estimates, what implications would that fact likely have on ground troop exposure or a potential ground troop study?

5. You stated that you were unaware of any studies other than the VA Proportionate Mortality Study on the relationship between lung cancer in humans and dioxin exposure. I have been told that the following article relates to this issue, and I would appreciate your assessment of the study reported in it:

Roberts, E.A., C.L. Golas, A.B. Okey. 1986. "Ah Receptor Mediating Induction of Aryl Hydrocarbon Hydroxylase: Detection in Human Lung by Binding of 2,3,7,8 TCDD." Cancer Research, Vol. 46, pp. 3739-3743.

Responses to Follow-up Questions for May 12, 1988 Hearing on Agent Orange Legislation and Oversight Issues from Senator Daschle, to the Office of Technology Assessment

1. In my view, we have learned a great deal already about exposure to Agent Orange in Vietnam, and there is a substantial and growing base of information about the possible health effects of dioxin. If dioxin had very large and severe effects on exposed populations, I think we would already know that from studies of populations heavily exposed occupationally and environmentally. The ongoing studies of occupational cohorts from the NIOSH dioxin registry, and, in the case of Agent Orange, the Ranch Hand study, will continue to refine our knowledge about the possible health effects of these chemicals.

2. I know of no methods, other than epidemiologic, for discovering possible associations of exposures with health effects occurring much later. It is important to assure that promising research opportunities are explored, and that those with merit are pursued. The NIOSH dioxin registry, for example, will continue to be a valuable tool for research in this area, given the appropriate resources. There are limits to the number of worthwhile studies that can be devised on a this topic, however.

3. In my opinion, the Ranch Hand exposure estimates, based largely on job category and the time and length of service, are excellent, much better characterized than either the Kansas study or the many methods that have been proposed for ground troop exposure estimates. Data from CDC's half-life study and the pilot study of Ranch Hand serum dioxin levels tend to confirm this.

4. Herbicide spraying other than Ranch Hand sprays are well known. The Joint Services and U S. Army Environmental Support Group has documented many of these in their computerized "Services Herbs Tape." They reported in September 1985, on 2,394 such missions by Army helicopters and ground equipment (truck, buffalo turbine, or backpack sprayer) and some Air Force missions that had been missed in the original National Academy of Sciences HERBS tape. It is impossible to assess definitively what this might have meant for those who sprayed herbicides or who were present when they were sprayed. At least some of the men in CDC's validation study must have been subject to such conditions, as they operated in III Corps, which had both Ranch Hand and other spraying. I think it is possible that some men, perhaps a relatively small number, actually had exposures of this kind that would leave them with elevated dioxin levels. That information was known and discussed for several years before the Agent Orange ground troop study was canceled.

5. I was referring to epidemiologic studies that directly linked dioxin or phenoxyherbicides to lung cancer. The study by Roberts, Golas, and Okey, concerns a possible mechanism by which 2,3,7,8-TCDD might interact with genetically determined factors to increase susceptibility to certain cancers induced by chemicals. In the study, ostensibly normal lung tissue was removed from 53 patients who were being operated on because of presumed lung cancer. Using radio-labeled 2,3,7,8-TCDD as a marker, they found that 10 of the specimens contained a protein known in animals to affect (indirectly) the metabolism of some known carcinogens. The authors conclude with the following statement: "Whether the forms of Ah receptor...in human tissues are genetically variable, and whether the concentration of receptor sites is a critical determinant of susceptibility to carcinogens remain to be determined." At present, this study is not useful in drawing a direct link between dioxin and lung cancer.

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Mike Shuppert

24 June 1988

Senator Alan Cranston
Chairman, Committee on Veterans' Affairs
Washington, DC 20510-6375

Dear Senator Cranston:

The following are answers to Senator Daschle's questions included with your letter dated 6 June 1988:

> "1. Please outline your contact with the Air Force management and the Ranch Hand scientists with respect to the Ranch Hand Study. Who briefs you on the study and/or Air Force policy? Does the Air Force ever request that you promote the Ranch Hand Study or study results?"

In 1978 the Ranch Hand Vietnam Association (RHVA) offered its wholehearted assistance to the Office of the Air Force Surgeon General following the commitment by the United States Air Force to Congress and the White House to conduct an epidemiological study of Operation Ranch Hand personnel who conducted herbicide spraying in Vietnam (1961-1971). The RHVA offered that same assistance to the Veterans Administration. The RHVA provided the U.S. Air Force with the names of Ranch Hand personnel, old copies of military orders containing names and serial numbers, and all information from RHVA records that might assist the U.S. Air Force with identification and location of former Ranch Hand personnel. When the U.S. Air Force launched the Air Force Health Study (AFHS), the RHVA stressed, and has continued to stress, the importance of this study to "the veterans of the Ranch", and encouraged Ranch Hand veterans to participate. (Participation from a cohort is a major key to an epidemiological study, and the RHVA has and will continue to encourage maximum participation.) (See Tab A and Tab B.)

The RHVA receives no special briefings regarding the AFHS, and certainly receives no briefings on Air Force policy! We receive copies of the AFHS's morbidity reports/mortality reports and lay summaries of those documents from the School of Aerospace Medicine or the Office of the Surgeon General, and we include those summaries in periodic newsletters to keep former Ranch Hand personnel informed regarding the progress and conclusions of the AFHS.

The U.S. Air Force has never requested any "favors" of the Ranch Hand Vietnam Association.

> "2. Have you discussed the 1988 Air Force report with anyone at the Air Force? If so, who? Please explain the nature of those conversations."

(See Tab C.) The RHVA wrote a letter to General Chesney and that letter is included herewith. The letter speaks for itself. The problems with USAFSAM TR-88-3 are articulated in the attached letter.

> "3. Why did you advise Ranch Handers not to participate in the Massachusetts Agent Orange study in a Ranch Hand Vietnam Association newsletter? Your newsletter contends that the Massachusetts study was 'questionable science.' What qualifies you to make that judgment?"

The Ranch Hand Vietnam Association did not advise against participation in the Massachusetts study, nor did it refer to the Massachusetts study as "questionable science". The February 1987 newsletter stated the problems with the Massachusetts study. The RHVA has from time to time consulted with recognized scientists when answers to questions of science are needed. The RHVA will continue to do so.

> "4. Referring to the Air Force Ranch Hand Study, you asserted in your testimony before the Committee that 'the conclusions of this ongoing study show no significant differences between Ranch Hand personnel and the matched comparison group.' Isn't it true that the 1984 Ranch Hand report, the recently released 1988 Ranch Hand update, and the adjusted analysis of the 1987 morbidity follow-up describe a number of health problems affecting significantly more Ranch Handers than veterans in the comparison group?"

The RHVA publishes the summaries of the mortality reports and morbidity reports of the AFHS as they become available. The RHVA makes no attempt to editorialize on those conclusions or challenge those conclusions -- we are not qualified to do so. The RHVA simply echoes the AFHS reports, and the veterans of the Ranch are free to accept them or reject them.

Regarding the "recently released 1988 Ranch Hand update", it is important to understand the context of USAFSAM TR88-3 (TR88-3). TR88-3 was written in its final form by one individual, the original draft being rejected by peer review. TR88-3 is not part of the AFHS; the author is not a member of the investigative team of the AFHS; and while it is an official U.S. Air Force document, it represents one individual's personal interpretation of data while totally ignoring more recently obtained morbidity data by the AFHS. Finally, USAFSAM TR-88-3 was published without peer review. (It is our understanding that peer review has been requested by both the U.S. House and Senate.)

Conclusion: Vietnam veterans of Operation Ranch Hand deserve and are entitled to hear the results of an epidemiological study dealing with our health -- unbiased and free of political pressures; i.e., pure science -- or as pure as today's climate will allow. Veterans of Ranch Hand have the greatest stake in the entire herbicide controversy and we are the cohort with the greatest degree of contact with herbicides. Our contact with herbicides was not casual -- imagined or conviently contrived: it was real! The aerial application of herbicides was our mission in Southeast Asia. We, more than any other group, have a right to see a hallmark epidemiological study reach whatever conclusions the science warrants. We are very proud of our mission during the Vietnam conflict and equally proud of our current contribution to medical science.

Thus far the conclusions of the Air Force Health Study are "reassuring". Should those conclusions change as the study continues, the Ranch Hand Vietnam Association will echo that information as well.

Respectfully,

Jack Spey

Jack Spey, Major USAF(RET)
President
Ranch Hand Vietnam Association

Enc. Tabs A, B, C and D

cc: Honorable G. V. Montgomery, with enc.
Honorable Frank H. Murkowski, wtih enc.
Honorable Thomas A. Daschle, with enc.

Ranch Hand Vietnam Association
850 Tarpon Dr.
Ft. Walton Beach, FL 32548
(904)243-5696

AIR FORCE HEALTH STUDY
(PROJECT RANCH HAND II)

Ⓐ

AN EPIDEMIOLOGIC INVESTIGATION OF HEALTH EFFECTS IN AIR FORCE PERSONNEL FOLLOWING EXPOSURE TO HERBICIDES

BASELINE MORBIDITY STUDY RESULTS

24 FEBRUARY 1984

Prepared for:
The Surgeon General
United States Air Force
Washington, D.C. 20314

George D. Lathrop, Colonel, USAF, MC
William H. Wolfe, Lieutenant Colonel, USAF, MC
Richard A. Albanese, M.D., GM-15
Patricia M. Moynahan, Colonel, USAF, NC

Approved for public release; distribution unlimited.

USAF SCHOOL OF AEROSPACE MEDICINE
Aerospace Medical Division (AFSC)
Brooks Air Force Base, Texas 78235

ACKNOWLEDGMENTS

The Principal Investigators gratefully acknowledge the outstanding support given to this project by:

The Ranch Hand Association and its elected officers, for sustained encouragement of the study, assistance in population ascertainment, and camaraderie and patriotism which contributed to unparalleled participation rates.

Our peer review groups, the University of Texas, School of Public Health, the Air Force Scientific Advisory Board, the Armed Forces Epidemiological Board, the National Research Council, and our Advisory Committee for their scientific contributions which have facilitated the conduct of this study and enhanced public credibility.

The Air Force Research Management Structure at the Aerospace Medical Division, Brooks AFB TX; 3303d Contracting Squadron, Air Training Command, Randolph AFB TX; Office of the Command Surgeon, Air Force Systems Command, Andrews AFB MD; and the Air Force Surgeon General's Office, Bolling AFB DC, for program advocacy and provision of resources.

The over 100 professionals, consultants, technicians, military and civilian, whose dedication and hard work over the past five years have made this report possible.

(B)

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VIET NAM

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Lt. Col. (Ret) Art McConnell
Lt. Col. (Ret) Rex Stoner
Lt. Col. (Ret) Bud Fisher

1 September 1983

Dear Veterans and Friends of Operation Ranch Hand:

When 97% of an elite group of American veterans (1266 in all) volunteer their time to aid our nation's scientific community, that's news! While not noted by the mass media, our efforts have been noted and are greatly appreciated by our country's scientific community and by our government.

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NINETY-SEVENTH CONGRESS

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CHAIRMAN

U.S. House of Representatives
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JOHN L. NAPIER, S.C.
JAMES L. NELLIGAN, PA.

December 17, 1982

I believe that all of the veterans of Operation Ranch Hand are to be congratulated for their wholehearted cooperation with the Department of Defense in their efforts to arrive at the conclusions of the first phase of the Ranch Hand II study.

Sincerely,

G. V. Montgomery
G. V. (SONNY) MONTGOMERY
Chairman

I applaud your unit's camaraderie and willingness to cooperate with scientific authorities conducting the Ranch Hand epidemiology study.

Sincerely,

Tom
Tom Daschle
Member of Congress

The Ranch Hands do this nation a great continuing service by their participation in the Air Force epidemiological study.

You and your associates have every reason to be proud of your service to this nation in war and in peace. I congratulate you for what you have accomplished in the past and for what you are now doing.

Sincerely,

John Paul
JOHN PAUL HAMMERSCHMIDT
Member of Congress

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
BOLLING AFB DC 20332

25 MAR 1983

Mr. Jack Spey
Ranch Hand Vietnam Association
850 Tarpon Drive
Fort Walton Beach, Florida 32548

Dear Mr. Spey

Preliminary reports on the Ranch Hand epidemiological study will be released in the next few months. The participation of the Ranch Hand members in this study has been very gratifying. Of the 1,198 eligible Ranch Hand members, 1,173 participated in the questionnaire phase of the study and 1,045 participated in the physical examination phase. This outstanding response exceeded even our optimistic expectations. Much of the success for the enthusiastic cooperation is due to you and your organization. I am very appreciative of the support you and the other Ranch Hand members have given this very important project.

I thank you all for another "mission" well done!

Sincerely

Max B. Bralliar

MAX B. BRALLIAR
Lieutenant General, USAF, MC
The Surgeon General

United States Senate
WASHINGTON, D.C. 20510

4 February 1983

I share your assessment of the professional accomplishments of our service personnel who so effectively executed Operation Ranch Hand.

Sincerely,

Jeremiah Denton

Jeremiah Denton
United States Senator

The men serving in operation Ranch Hand were indeed unique and we owe them a debt of gratitude.

You have all been of great assistance to this country in your contributions while on duty in Vietnam.

Sincerely,

Alan K. Simpson

The above are partial excerpts.

file copy Ⓒ

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SMSgt (Ret) Pappy Rothermel
MSgt (Ret) Lee Harrison
MSgt (Ret) Al Nicolas
Mike Shuppert

17 April 1988

Lieutenant General Murphy A. Chesney
United States Air Force Surgeon General
Headquarters United States Air Force
Bolling AFB, DC 20332

Dear General Chesney:

On 2 April 1988 the Ranch Hand Vietnam Association received from your office a copy of USAFSAM-TR-88-3, "USAF Personnel and Exposure to Herbicide Orange", dated February 1988.

After thorough review it is obvious that this document attempts to challenge the conclusions of the 1984 morbidity portion of the Air Force Health Study (AFHS) dealing with possible health effects associated with the USAF defoliation mission in Southeast Asia.

It is also apparent that the author, a member of that study in its early stages, totally ignored the 1987 morbidity results of that same study and the scientific conclusions drawn from that most recent data.

Most disturbing is the fact that this document was published without scientific peer review and emanated from outside of the regular chain of command dealing with the AFHS.

The Air Force Health Study (AFHS) represents a hallmark epidemiology study, one that has and will continue to be a model for future epidemiological investigations dealing with occupational/health risks, and the United States Air Force can indeed take great pride in its authorship and its management to date.

It would indeed be unfortunate for all concerned if USAFSAM-TR-88-3 is allowed to erroneously cast doubts on the validity of the AFHS's ongoing conclusions, a study continually reviewed and monitored by our nation's experts on dioxin and its effect on man.

The "Agent Orange" controversy, for numerous reasons, has been affected by more than its share of bad science and its echoing press coverage. Sensing that this document, USAFSAM-TR-88-3, has questionable and less than scientific motives, the Ranch Hand Vietnam Association requests that USAFSAM-TR-88-3 be reviewed by the Agent Orange Working Group, or other appropriate peer review groups, to determine the validity of its conclusions. If this document is found to be faulty or flawed, it should be withdrawn by the United States Air Force. The AFHS and its conclusions should not be clouded by a document unreviewed by scientists and written by one uninvolved individual.

The Air Force Health Study (AFHS) represents a landmark scientific effort conducted by this country -- with far greater ramifications than its effect on the American veteran. All current and future litigation dealing with the dioxin/human relationship may well rest on the results of the Air Force Health Study.

Respectfully,

Jack Spey, Major USAF(RET)
President
Ranch Hand Vietnam Association

Ranch Hand Vietnam Association
850 Tarpon Drive
Ft. Walton Beach, FL 32548
(904)243-5696

JS:mt

cc: Senator Alan Cranston, Chairman
  Senate Veterans Affairs Committee
 Representative G. V. Montgomery, Chairman
  House Veterans Affairs Committee
 Dr. Don Newman, Undersecretary
  Department of Health and Human Services
 Colonel Jeffrey G. Davis, Commander
  School of Aerospace Medicine
 Mr. Fred Conway, Executive Secretary
  Veterans Administration Environmental Hazards Committee

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TSgt. (Ret.) Keith Yale
SMSgt. (Ret.) Pappy Rothermel
MSgt. (Ret.) Lee Harrison
MSgt. (Ret.) Al Nicolas
Mike Shuppert

17 February 1987

Dear Rancheros:

Just before press time the Association learned that a significant number of Ranch Hand veterans had received a letter from the Massachusetts "Agent Orange" Program requesting Ranch Hand participation in a Fat Biopsy Study being conducted at the Massachusetts General Hospital.

As a result of consultation the Association learned that the principal investigator had been criticized for the methodology of the investigation,and the previous conclusions expressed by the same authors, in testimony given to the Veterans Administration Advisory Committee on Environmental Hazards on November 17, 1986. After careful review, this study does not appear to be good science, i.e.: employing good scientific principles, techniques and the fair objective analysis of data.

The Ranch Hand Vietnam Association does not endorse this study and was not a party to the Massachusetts "Agent Orange" Program receiving our addresses.

This program does not have the support of the United States Air Force.

The letter and entire subject should be viewed with certain skepticism.

Ranch Hand Mortality Update:

The following is an excerpt from an Air Force news release dated 10 February 1987:

"The U.S. Air Force today released the fourth mortality report of its Ranch Hand (Agent Orange) study. This report is a part of a 20-year epidemiological investigation to determine whether there are possible adverse health effects from herbicide exposure to Air Force members who conducted aerial spraying missions in Southeast Asia (Operation Ranch Hand).

"This fourth mortality analysis, like the preceding three, released in 1983, 1984 and 1985 respectively, has not demonstrated any health effects which can be conclusively attributed to herbicide or dioxin exposure

**Office of the
Administrator
of Veterans Affairs**

Washington DC 20420

**Veterans
Administration**

JUL 1 1988

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find the Agency's response to the question which you forwarded on behalf of Senator Tom Daschle for the May 12, 1988, hearing by the Senate Veterans' Affairs Committee. Thank you for the opportunity to provide this additional information for the record.

Sincerely,

THOMAS K. TURNAGE
Administrator

Enclosure

cc: Honorable Frank H. Murkowski
Honorable Thomas A. Daschle

"America is #1—Thanks to our Veterans"

Question: You mentioned that the Agent Orange Registry addresses are out of date. What efforts have been made to keep the list updated? Would we be able to contact the Registry population to notify veterans of a health risk if one were identified? Does the VA plan to update this list so that registrants could be notified if necessary?

Response: Since the Agent Orange Registry was initiated in early 1978 over 230,000 concerned Vietnam veterans have participated in the examination process. Recent mailout efforts to registry participants resulted in a significant number of mailouts being returned to the Veterans Administration (VA) as undeliverable because of address changes. No special effort is being undertaken or planned at this time to provide for an updating of addresses. To date, there is still no scientific or medical consensus that the possible exposure of Vietnam veterans to Agent Orange has had an adverse health effect on these individuals. Should future research results make it necessary to notify specific veterans or Vietnam veterans in general, the VA would consider updating the addresses utilizing the assistance of various resources including, but not limited to, internal VA listing, the U.S. Postal Service, Social Security Administration, various veterans service organizations and other sources. Efforts could also be made to request veterans' addresses, through the use of the media (i.e., television, radio, newspapers, etc). These extensive efforts would be undertaken only when there is a demonstrated scientific or medical basis for doing so. Under most circumstances an announcement of the research results and the suggested actions for the veterans to take would be made through the public media and should be more effective in reaching all the affected veterans.

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

ROBERT WOOD JOHNSON MEDICAL SCHOOL

[formerly RUTGERS MEDICAL SCHOOL]

Department of Environmental and Community Medicine
Division of Occupational Health
Piscataway, New Jersey 08854 (201) 463-4771

July 22, 1988

Honorable Alan Cranston
Chair
Senate Committee on Veterans Affairs
Washington, DC 20510-6375

Dear Senator Cranston:

This is a belated response to the question put to Wayne Wilson by Senator Daschle as a followup to the May 12, 1988 hearing.

Q. Please explain how the methodology employed by the New Jersey Agent Orange Commission allows scientists to distinguish between "background" dioxin and dioxin from Agent Orange? What are the implications of this technology?

In controlled laboratory experiments it is possible to tag or label a molecule with a radioactive atom such that it can be identified in its travels through organisms or the environment. In the real world, there is no ready way to identify whether a specific molecule of dioxin has entered the body because of herbicide exposure or from some other source.

There are two important considerations. There are many different kinds of dioxin, but the one that is of concern to veterans is called 2,3,7,8-TCDD. The numbers refer to the locations of chlorine atoms on the dioxin molecule. We are all exposed to a variety of dioxins in air, water, and food, including a small amount of 2,3,7,8-TCDD. If we test an individual we would expect to find a certain amount of a dozen different dioxin compounds. When we tested the exposed veterans we found that they were higher in 2,3,7,8-TCDD and ONLY this compound. None of the other dioxins were elevated in our exposed veterans compared to controls. For this reason one can be confident that we have a group of people exposed specifically to 2,3,7,8-TCDD.

In order to ascertain that this was likely to be herbicide exposure in Viet Nam, rather than some other source of 2,3,7,8-TCDD, we designed our study so that each exposed man (herbicide handler in Viet Nam) was matched to a Viet Nam vet who had no known exposure, as well as to a Viet Nam era vet (who had not gone to Viet Nam).

Because the 2,3,7,8-TCDD was elevated in the exposed Viet Nam vets and not in either other group we can be confident that we were looking at exposure that occurred in Viet Nam and was associated either with herbicide handling per se, or with some other factor common to the herbicide handlers but not to other Viet Nam vets.

Thus we are dealing not with a specific technology but with an epidemiologic design. The implications of our study are that it is possible to detect elevated 2,3,7,8-TCDD ("dioxin") levels in exposed veterans nearly 20 years after exposure. This can be used as the elusive measure of exposure for which other researchers have been seeking.

I am sorry that I was not available to answer this question sooner.

Sincerely yours,

Michael Gochfeld

Michael Gochfeld, M.D., Ph.D.
Director of Occupational Medicine

Attachment #5

USAFSAM-TR-88-3

UNITED STATES AIR FORCE PERSONNEL AND EXPOSURE TO HERBICIDE ORANGE

Richard A. Albanese, M.D.

February 1988

Interim Report for Period March 1984 - February 1988

Approved for public release; distribution is unlimited.

USAF SCHOOL OF AEROSPACE MEDICINE
Human Systems Division (AFSC)
Brooks Air Force Base, TX 78235-5301

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6b. OFFICE SYMBOL *(If applicable)*
USAFSAM/RZM

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6c. ADDRESS *(City, State, and ZIP Code)*
Human Systems Division (AFSC)
Brooks Air Force Base, TX 78235-5301

7b. ADDRESS *(City, State, and ZIP Code)*

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Albanese, Richard A.

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Epidemiologic Investigation
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Dioxin
Ranch Hand
Air Force Health Study

19. ABSTRACT *(Continue on reverse if necessary and identify by block number)*

The United States Air Force is conducting an epidemiological study, called the Air Force Health Study (AFHS), to determine whether or not military personnel associated with herbicide spraying during the Vietnam War have experienced any adverse health effects. This report reviews salient findings of the AFHS first morbidity report published in 1984, and presents new work by examining relationships between AFHS findings and the results of laboratory toxicological studies and other epidemiological studies addressing dioxin. Eleven clinical areas have been emphasized based on a toxicological profile developed from the literature and availability of data in the AFHS: weight loss, neoplasia, birth defects, neurological changes, psychological changes, hepatotoxicity, chloracne, cardiovascular changes, immunological deficits, endocrine changes, and mortality. In six of these eleven clinical areas, statistically significant group differences occurred, and in five of these six instances the group differences were in the direction of expected dioxin

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19. ABSTRACT (Continued)

effects. Dioxin cannot be confidently identified as the causative agent of these findings at this time because of several reasons, including the absence of correlations with an exposure index and the incomplete clinical picture. However, dioxin is not exonerated as a causative agent because of the directionality of the observed group differences and the preliminary nature of the exposure index used in the AFHS first morbidity report.

Study Design

The study design is a matched cohort design in a nonconcurrent prospective setting. The study addresses mortality and morbidity and includes long-term follow-up activities. A detailed population ascertainment process identified 1,278 Ranch Hand personnel who served in Vietnam during the period 1962 through 1971, when the spraying operation was active. A comparison group was formed by identifying all individuals assigned to Air Force organizational units with a mission of flying cargo to, from, and in Vietnam during the same period. A computerized nearest neighbor selection process was used to match up to 10 comparison individuals to each Ranch Hand. This matching was done by job category, race, and age. The initial comparison group erroneously contained some individuals who did not in fact have any Southeast Asia experience. These individuals (18%) were removed from the comparison population after detailed hand record review, leaving an average of approximately eight comparison individuals matched to each Ranch Hand.

The comparison individuals matched to each Ranch Hand were listed in random order within each set. The first five comparisons were included in the mortality analyses giving these studies a 1:5 design. For each living Ranch Hand, the first living member of his randomized comparison set was selected for participation in a morbidity study consisting of an in-home interview and a comprehensive physical examination. If the matched comparison subject declined to participate or subsequently withdrew from the morbidity study, that individual was replaced by the next living comparison subject from the randomized set who was willing to participate.

Follow-up studies are an important aspect of the AFHS. The follow-up studies consist of mortality and morbidity components. Each Ranch Hand and his set of comparisons will be the subject of mortality evaluations for the next 20 years. In addition, follow-up questionnaires and physical examinations are being offered to participants in 1985, 1987, 1992, 1997, and 2002 in order to bracket the latency periods associated with possible attributable disease.

Inference Concerning Herbicide Causation

In an experiment, members from a single population are randomly assigned to either a treatment (exposed) or control group. In the setting of such completely randomized designs, statistically significant differences between the treated and control group can often be reliably ascribed to the effect of the exposure. The AFHS is the study of an unplanned environmental exposure and thus does not follow the above experimental design. The study has a nonrandomized design and is an observational study. In such studies, while the comparison group is chosen to be similar to the exposed group with respect to as many qualities as possible, except exposure status, in the absence of randomization, group differences or the lack thereof cannot be interpreted solely in terms of exposure. For example, in the AFHS the exposed group was stationed in the Republic of Vietnam itself, while most of the comparison group was quartered in surrounding areas such as Okinawa and Japan. Comparison aircrew members periodically flew into Vietnam while comparison ground support personnel, predominantly enlisted, remained in non-combat areas. Ranch Hand Vietnam tour length was approximately 1 year while comparison tour length was 3 years. These differences and others may or may not influence health and longevity. Thus, group differences or the lack thereof cannot unambiguously be ascribed to herbicide exposure. This emphasizes the importance of relating study results to other studies to see whether common patterns of effect emerge.

Another approach to inference is the use of an exposure measure or index. If one knew exactly how much herbicide each Ranch Hand was exposed to, highly exposed individuals could be contrasted with less exposed individuals within the Ranch Hand group and an estimate of herbicide effect could be constructed. However, once again, since randomization was not employed in the dose assignment, estimates of herbicide effect must be viewed with great care due to the possibility of confounding factors. For example, it could happen that higher exposures occurred for a variety of reasons in the lower socio-economic strata (lower ranks) of the Ranch Hand cohort. Industrial hygiene data concerning herbicide exposure were not collected during the Vietnam era. In any case, however, the use of an exposure index provides another view of exposure effects which can augment interpretation of group differences.

The exposure index used in this report relates to the TCDD-containing herbicides: Herbicide Orange, Herbicide Purple, Herbicide Pink, and Herbicide Green. Archived samples of Herbicide Purple had a mean TCDD concentration of approximately 33 ppm, and archived samples of Herbicide Orange had a mean concentration of 2 ppm. Herbicides Pink and Green contained twice the 2,4,5-T of Herbicide Purple and, therefore, have been estimated to contain TCDD at a concentration of approximately 66 ppm.

Using mission records, it was possible to determine the amount of each herbicide sprayed each month in Vietnam as well as the number of Ranch Hands in each job category who were involved in spraying that month for the period 1962 through 1971. Tour data also allowed determination of the months each individual was involved in the Ranch Hand operation. Using these data, an exposure index was developed for each Ranch Hand. The exposure index is directly proportional to the number of gallons of herbicide sprayed in Vietnam during the individual's tour, where potential exposure to the higher TCDD-containing herbicides (Purple, Pink, Green) has been properly scaled according to dioxin concentration to place them on the same basis as Herbicide Orange. Also, the exposure index is inversely proportional to the number of airmen assigned to the specific subject's job category during his tour.

From the description just given, it should be clear that the current Ranch Hand exposure index is an estimate only, as it applies theater-wide spraying to a single individual, and, since it assumes that all individuals in a job category were equally exposed. Also, the degree to which this calculated index is associated with actual body burden of TCDD is unknown. In short, the absence of a positive association between the index and health outcomes cannot be taken as confirming a lack of herbicide effect, nor can the presence of an association be interpreted as an unambiguous herbicide effect without consideration of possible confounding factors.

Job category matching in the AFHS used five categories: (a) officer-pilot, (b) officer-navigator, (c) officer-other, (d) enlisted-flying, and (e) enlisted-ground. Exposure index analyses used three occupational categories: all officers were combined into one category called "officer" due to the fact that navigators and pilots, while having different jobs, were believed to be exposed in the same manner. For each exposure occupational group (officer, enlisted-flying, enlisted-ground), the calculated exposure index was trichotomized into three levels: low exposure, medium exposure, and high exposure. Since the mode of exposure was judged to be different in each occupational group, statistical analyses with the exposure index were occupational group specific.

Questionnaire and Physical Examination

The AFHS uses a broad medical history and physical examination. The medical history was collected by an extensive in-home questionnaire.[3]

The purpose of the extensive questionnaire was to collect data that could be analyzed for the subjective presence of adverse health effects that might be related to herbicide exposure. In addition to the study participants, the questionnaire contractor was also required to interview the participants' current and former wives, as well as the first-order next-of-kin of deceased individuals to obtain morbidity data as completely as possible.

Physical examinations were performed at a single location by a contractor. All examiners evaluated the participants without knowledge of their exposure status. The number of examiners and the turnover of staff members were kept to a minimum to limit between-examiner variability. All laboratory tests were subjected to rigid standards of quality control, and laboratory and physical examination data were measured on a continuous scale whenever possible to improve statistical power in the analysis.

A general summary of the major components of the examination is presented in Table 1, and the laboratory procedures conducted on each subject are listed in Table 2.

In the AFHS, cumulative mortality as of 31 December 1984 displays no statistically significant overall Ranch Hand-comparison differences. Summary counts of death and age standardized mortality ratios (SMR) by rank and occupation are given in Table 18.

TABLE 18. SUMMARY COUNTS, SMRs AND P VALUES FOR DEATH BY RANK AND OCCUPATION

	Ranch Hand			Comparison				
Rank	At Risk	Dead	Rate	At Risk	Dead	Rate	SMR	P Value
Officers	466	16	.034	2278	98	.043	.791	.37
Enlisted	791	39	.049	3893	187	.048	1.03	.89
Occupation								
Flying	646	24	.037	3163	161	.051	.726	.13
Ground	611	31	.051	3008	124	.041	1.23	.33

Further study of these mortality data discloses complex patterns with date of birth (which is related to date of service in Vietnam) and date of death.

CONCLUSION

In this report, eleven clinical areas have been emphasized based on a clinical toxicological profile developed from the literature concerning animal and human responses to dioxin and availability of data in the AFHS. Table 19 lists the general toxicological effects anticipated on the basis of the literature and also summarizes Ranch Hand findings. The toxicological profile we have developed from the literature certainly has an element of subjectivity as articles were selected and interpreted from a very large literature. Similarly, each observation in the AFHS can be challenged, and some specific caveats have already been mentioned.

TABLE 19. SUMMARY OF FINDINGS*

Toxicological Effect Suggested by Animal and Human Literature on Dioxin	Observation In AFHS
Weight Loss	o
Increased Neoplasia	+
Increased Birth Defects	+
Neurological Changes	o
Psychological Changes	+
Hepatotoxicity	+
Chloracne	o
Cardiovascular Changes	+
Immunological Deficits	o
Endocrine Changes	+/-
Increased Mortality	o

* "o" indicates no group differences observed
"+" indicates group difference observed in expected direction
"-" indicates group difference observed but in opposite direction

At this time one cannot ascribe the observed group differences to an effect of dioxin. One cannot implicate dioxin for at least four reasons: (a) the exposure index completely failed to demonstrate any association between increased exposure and increasing adverse outcome; (b) the full clinical profile for dioxin was not realized with the absence of chloracne being particularly noteworthy; (c) uninvestigated confounding variables remain for several of the target clinical endpoints, and resolution of these issues may alter the observed group differences; and (d) the effect of multiple statistical testing is not well defined.

However, the AFHS does not exonerate dioxin as a causative agent of these group differences. This conclusion is supported by three reasons: (a) in six of eleven clinical variables, statistically significant group differences occurred, and in five of these six instances the group differences were in the direction of expected dioxin effects; (b) uninvestigated confounding variables remain for several of the targeted clinical endpoints and resolution of these issues could alter group differences; and (c) the currently available exposure index is only an indication of exposure with unknown precision.

The overall probability of obtaining the AFHS results under the hypothesis of no group difference is not known. The summary in Table 19 cannot be used for statistical inference at this time because the table summarizes the results of hundreds of potentially correlated tests of significance. Further clarification of the role of dioxin in human health must await the results of the follow-up phases of the AFHS and other ongoing epidemiologic studies of dioxin-exposed groups.

DEPARTMENT OF DEFENSE

DEPARTMENT OF THE AIR FORCE
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235-5301

2 MAY 1988

Honorable Alan Cranston
United States Senate
Washington DC 20510-0001

Dear Senator Cranston

I attended a meeting on 18 April 1988 to discuss the Air Force Health Study with Mr Jonathan Steinberg and other staffers of both the Senate and House Veterans Affairs Committees. At that meeting, Mr Steinberg requested that I prepare a statement outlining my involvement in the preparation and release of the USAF School of Aerospace Medicine Technical Report 88-3, authored by Dr Richard Albanese. The following information is provided in response to Mr Steinberg's request. I hope it is helpful to you and your committee in your deliberations on Agent Orange issues.

1984

The Baseline Morbidity Report of the Air Force Health Study (AFHS) was released in February 1984. At that time, all four Principal Investigators felt that the report could not be accurately characterized as a "negative" report, but Dr Albanese felt more strongly than the others that subclinical laboratory findings and statistical interactions observed in the data might represent actual herbicide/dioxin effects. This view was not apparently shared as strongly by Dr Robert Miller or other members of the Advisory Committee. Dr Albanese subsequently started to conduct a review of dioxin research in order to begin the preparation of a report outlining the toxicological profile of dioxin.

Dr George Lathrop and Col Patricia Moynahan retired in August and September 1984 and I became Chief Principal Investigator. Dr Albanese was reassigned to other mathematical duties in his branch and became Chief of the Radiation Analysis Branch, Radiation Sciences Division, when the Data Sciences Division was reorganized.

1985

Dr Albanese completed his literature review, began to develop his profile of potential dioxin effects in animals, and began to contrast these findings with the results of the examinations as reported in the February 1984 document.

1986

In 1986, Dr Michalek and I worked with Dr Albanese on reviewing and modifying drafts of the report. We had agreed to be coauthors, since the report expanded on previously published summaries of the 1984 report. Some additional analyses of the baseline data were completed, primarily in the area of reported birth defects.

1987

A finalized version of the report was prepared in early 1987, and was forwarded for internal review within the School of Aerospace Medicine. Delays in the review occurred due to questions as to which journal would be most likely to accept and publish such a long article (in excess of 50 typewritten pages). The initial plan was to submit it to the American Journal of Epidemiology. However, we continued to have concerns that it would be unsuitable for publication in that or other medical journals due to its excessive length. I signed the review/approval document for the report on 26 June 1987. Delays were also caused by conflicting priorities from the effort to begin the second followup examination phase of the AFHS. The School of Aerospace Medicine review was completed on 22 July 1987.

A copy of the approved report was sent to Dr Robert Miller, Chairman of the Advisory Committee, on 3 November 1987. We requested his critique of the report in his official capacity, and also asked his advice on strategies to submit the article for publication.

1988

We received a telephonic response from Dr Miller in mid-December and his written response to the article was mailed on 13 January 1988. Dr Miller and the other committee members were critical of the report and recommended that it not be published due to its excessive length, its nontraditional format, and its "old" data. They did suggest that a rewritten article should be prepared based on data from the report issued in October 1987. Dr Michalek worked with Dr Albanese to rewrite the report, but he was unsuccessful. Dr Michalek and I felt that we could not agree with the tone and style of the report as written by Dr Albanese, and we subsequently withdrew our names as authors. Dr Albanese made plans to submit the article for publication as a technical report, rather than as a normal AFHS report.

While these events took place, Senator Daschle requested a meeting to discuss the Air Force study. The requested meeting was held on 21 January and was attended by Dr Albanese, Dr Michalek, Brigadier General Rufus Dehart of the Surgeon General's Office, and me. At that meeting, a commitment was made to provide a copy of the report that subsequently became the USAFSAM TR 88-3 to the senator.

The technical report (USAFSAM TR 88-3) was released in February, in accordance with the usual Air Force procedures for technical reports. This report did not receive the reviews or distribution normally given to reports on the AFHS, since it dealt with previously released data from the study.

Senator Daschle was provided with a copy of the technical report, and he released the TR and his interpretation of the data it contained on 21 March 1988.

Sincerely

William H. Wolfe

WILLIAM H. WOLFE, Col, USAF, MC
Chief, Epidemiology Division

DEPARTMENT OF THE AIR FORCE
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235-5301

The Honorable Alan Cranston
Chairman, Veteran's Affairs Committee
414 Senate Russell Building
Washington, DC 20510

28 April 1988

Dear Mr Chairman

I attended a meeting with the staffers of the Senate and House Veteran's Affairs Committee on 18 April 1988 and was asked by Mr Steinberg to provide you a statement addressing my involvement in USAFSAM-TR-88-3. This is found in the following.

I was a principal investigator during the time period 1978 through October 1984 on the Air Force Health Study addressing the possibility of health effects in Air Force personnel who sprayed herbicide orange in Vietnam. I am the author of USAFSAM-TR-88-3, "United States Air Force Personnel and Exposure to Herbicide Orange." This statement describes, to the best of my ability, the history of the development of that report.

As a principal investigator, I was a coauthor of the February 1984 Air Force report, "An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides. Baseline Morbidity Study Results." I agreed with the report statement that "there is insufficient evidence to support a cause and effect relationship between herbicide exposure and adverse health in the Ranch Hand group at this time." I also believed at that time that there was insufficient evidence to safely dismiss the possibility that dioxin had been or was at that time active in effecting the health of the Air Force personnel who sprayed the material in Vietnam (the Ranch Hands). I believe that the February 1984 report implicitly recognized the fact that there was insufficient evidence to dismiss dioxin as a possible offender since the report clearly points to future research commitments (please see Chapter XVIII of the report). A second motivation for writing USAFSAM-TR-88-3 was to provide updated thinking concerning systemic cancer and birth defects.

I returned to my usual research duties emphasizing the biomedical aspects of radiation exposure in October 1984, but I was permitted to interact with the Ranch Hand research team and pursue study of the baseline study results. I continued to collect articles addressing the toxicology of dioxin through 1985 and 1986 and began to write an interpretive article in 1986. In 1986, I submitted at least two drafts of the article to Col William Wolfe and Dr Joel Michalek, the current study principal investigators. They carefully critiqued the work, with Col Wolfe emphasizing medical aspects and Dr Michalek emphasizing statistical aspects. In January 1987, I submitted a final draft to Col Wolfe and Dr Michalek which they signed and subsequently forwarded to the United States Air Force School of Aerospace Medicine for clearance. Clearance was obtained and the article was subsequently forwarded to the research program's peer review group for their evaluation of the article as a potential candidate for publication in the Journal of the American Medical Association. A written response from the peer review group was received in January 1988. The peer review group suggested revisions which included format changes appropriate for the Journal of the American Medical Association and the addition of data from the 1987 report titled "Air Force Health Study: An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides. First Followup Examination Results." These changes would have delayed the report publication for more than one year without changing its basic conclusion, which conclusion was not disputed, to my knowledge, by the peer review group. In February 1988, I received official permission to publish the document as a United States Air Force School of Aerospace Medicine technical report and did so.

Sincerely

Richard A. Albanese MD

Richard A. Albanese, MD
Chief, Radiation Analysis Branch
Radiation Sciences Division

DEPARTMENT OF DEFENSE

DEPARTMENT OF THE AIR FORCE
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235-5301

27 April 1988

Honorable Alan Cranston
United States Senate
Washington DC 20510-0001

Dear Senator Cranston

A meeting was held on 18 April 1988 at the request of staffers of both the Senate and House Veterans Affairs Committees. The purpose of that meeting was to discuss the current status of the Air Force Health Study. At that meeting, I was asked to provide you with information outlining my involvement in the preparation of the USAF School of Aerospace Medicine Technical Report 88-3. The following information is provided in response to that request.

1984

Dr Albanese began a literature review of dioxin research shortly after the release of the Baseline Morbidity Report in February 1984, in preparation for his writing of the subject technical report. At that time, I was a mathematical statistician in the Biomathematical Modeling Branch, Data Sciences Division; Dr Albanese was the Branch Chief and was a Principal Investigator of the Air Force Health Study (AFHS).

Dr George Lathrop and Col Patricia Moynahan retired from the Air Force and Col Wolfe became Chief Principal Investigator. Dr Albanese was removed from the AFHS team and was reassigned to other full time duties in his branch. He subsequently was assigned to the Radiation Analysis Branch, Radiation Sciences Division, and I took his place as a Principal Investigator.

1986

In 1986, Dr Albanese, Col Wolfe and I agreed to collaborate and began to review drafts of the report that Dr Albanese had prepared. Dr Albanese asked that I analyze data that had been presented in the 1984 Morbidity Report but which had not been analyzed statistically. That data had classified reported birth defects by group and by severity. I carried out the analysis, which showed that the previously observed difference in birth defects between the Ranch Hands and the Comparisons did not change with the severity of the reported birth defects. I also added additional material on sample size considerations and wrote statistical caveats throughout the report.

1987

I believe it was in early 1987 when a complete draft was handed to Col Wolfe for his comments. Dr Albanese did the bulk of the writing; he wrote the conclusion section and I inserted the statistical caveats as described. The report was initially submitted for review within the School of Aerospace Medicine in March 1987, with plans to submit it for publication in the American Journal of Epidemiology. However, we had concerns that it would be unsuitable for publication in that or other medical journals due to its excessive length. I signed the review/approval document for the report on 19 March 1987 because I felt that the paper had been sufficiently caveated and because I was concentrating on the technicalities of the analyses rather than on the style of the paper. The School of Aerospace Medicine review was completed on 22 July 1987.

A copy of the report was sent to Dr Robert Miller, Chairman of the Advisory Committee, for his review and advice on which journal would be most appropriate for the article on 3 November 1987.

1988

We received Dr Miller's written response to the article (dated 13 January 1988) in mid-January. He criticized the report as badly written and uninteresting since it contained only baseline data from a report that was four years old. I related these comments to Dr Albanese, telling him that the committee had suggested very strongly that the report was not suitable for publication. At that time, Col Wolfe, Dr Albanese and I were asked to attend a meeting with Senator Daschle to discuss the AFHS. At that meeting, on 21 January, the Senator expressed concern that we had not published corrections to the baseline birth defect analysis, the cancer analysis and had not released data on the results of the pilot serum dioxin study. We indicated that we had coauthored a paper with CDC scientists on the pilot study and that it would be submitted for publication soon. Regarding the birth defect issue, we said that the analysis had been corrected and had been included in the coauthored paper, but that the paper had been heavily criticized by the Advisory Committee. We committed to try to edit the report to address the concerns of the committee and release it as a Technical Report. We subsequently received a letter and phone calls from the Senator confirming our commitments to publish the dioxin assay results and the technical report.

I tried to edit the report to address the concerns of the committee and found that I could not do so without a complete rewrite. I carefully considered the report and felt that I should remove my name from the authorship. I told Col Wolfe of my decision and he agreed to remove his name as well. I told Dr Albanese of our decision since we regarded the paper as an expression of his opinions rather than our own. I subsequently signed the new approval form because I believed that we had committed ourselves to releasing the report, and because it was technically a correct report.

Sincerely

Joel E Michalek

Joel E. Michalek, PhD
Chief, Biometrics Branch
Epidemiology Division

Office of General Counsel Washington, D.C. 20420

Veterans
Administration

JUL 27 1988

In Reply Refer To:

Honorable Alan Cranston
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in response to your request for the views of the Veterans' Advisory Committee on Environmental Hazards on a report entitled, "United States Air Force Personnel and Exposure to Herbicide Orange" by Dr. Richard Albanese. The full Committee is not scheduled to meet until November 1988. However, the Chairman of the full Committee and the Chairman of the Scientific Council, in an effort to be responsive to your request in a timely manner, convened a telephone conference on May 27, 1988, of the members of the Dioxin Panel of the Scientific Council, to discuss this report.

The panel agreed that the report is flawed in a number of ways. The most significant criticism of the Panel was that the author used data derived from the first morbidity report of the Air Force Health Study published in 1984 and gave no reference to more recent morbidity data published in 1988. The panel thought this important because many of the trends observed in the 1984 data did not continue in the 1988 data. Therefore, many of the inferences derived from the 1984 data were incorrect when reviewed in the light of the 1988 data.

Concern was also expressed by the apparent reliance by the author on animal data as being predictive of human experience. This concern was based upon the fact that there is widespread species variability in terms of observed effects of exposure to dioxin and that the animal data are not replicated in much of the human exposure experience. There was also concern about the use of unvalidated, self-reported data on the occurrence of birth defects among progeny of the Ranch Hand population and that some of the trends identified by the author were not supported by the data contained in his report.

The Panel members did note that the author expressed some caution in interpreting his study. However, they believed that the author's failure to give recognition to the 1988 data was a serious flaw and considerably reduces the pertinence of this report.

I am sending an identical letter to Senator Murkowski and to Representatives Montgomery and Solomon.

Sincerely,

Frederic L Conway

FREDERIC L. CONWAY
Executive Secretary,
Veterans' Advisory Committee
on Environmental Hazards

Comments on the Statement of
Thomas A. Gasiewicz, Ph.D.
before the
Senate Veterans' Affairs Committee

Dr. Gasiewicz points out what is well-known to persons familiar with the literature in toxicology, that animals given relatively large doses of 2,3,7,8-tetrachlorodibenzo-p-dioxin (dioxin) exhibit certain types of toxic effects, and that there are extremely large differences from species to species of experimental animals in the amount of dioxin required to produce an effect. He then lists several specific types of effects (chloracne, body weight loss, immunosuppression, carcinogenesis, and AH receptor binding) which he asserts are consistently found in all experimental animal studies, and suggests that one can deduce that similar toxic effects are likely to be seen in humans. He points out, correctly, that one toxic effect of dioxin, chloracne, has been observed in humans, but that more subtle responses, such as cancer development and alterations of immune function, have not been conclusively demonstrated to occur in humans, and may never be. He also points out, correctly, that humans differ biologically from experimental animals in many ways.

The last point is particularly important. Lacking any kind of confirmatory evidence, it would be mistaken to infer that the human response to dioxin would be equivalent to that of experimental animals. In fact, the few bits of knowledge that we do have about human response could lead us to infer with equal certainty that humans are among the most resistant animals to the toxic effects of dioxin.

One of the major drawbacks of the data on humans is the lack of evidence that would enable the calculation of a dose-effect relationship between dioxin exposure and adverse health. That situation may change now that there exists a method to measure with great precision the amount of dioxin found in human blood serum. If it can be demonstrated that higher levels of serum dioxin are associated with increased frequencies of certain types of health effects, the case would be clear. This has not been done.

With regard to the proposed legislation, the point that must be kept in mind is that no increased frequency of adverse health effects has been observed in Vietnam Veterans, not even in the Ranch Hands, the group most heavily exposed to Agent Orange. This is true even for chloracne, a sensitive indicator of dioxin exposure and an effect which is most distinct and would have been most easily observed had it occurred. In the light of these facts, it would be neither scientifically sound nor appropriate for the Veterans Committee on Environmental Hazards to recommend that the current guidelines be modified in any way.

June 24, 1988 Armon F. Yanders

UNIVERSITY OF ROCHESTER
School of Medicine and Dentistry

ENVIRONMENTAL HEALTH SCIENCES CENTER
Toxicology Training Program

October 17, 1988

Honorable Alan Cranston
Chairman, Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510-6375

Dear Senator Cranston:

Enclosed you will find my responses to comments made by representatives of the Environmental Protection Agency, Office of Technology and Assessment, National Cancer Institute, and Centers for Disease Control, Agent Orange Working Group, and the Veterans' Administration in response to my testimony at the May 12, 1988 hearing on Agent Orange related issues.

Please feel free to contact me if I can be of any further assistance.

Sincerely,

Thomas A. Gasiewicz, Ph.D.
Associate Professor of
Biophysics

Mailing address: University of Rochester School of Medicine,
P.O. Box EHSC, Rochester, New York 14642

Responses to Comments on the Writtin Testimony of Dr. Thomas A. Gasiewicz Submitted at the Veteran's Affairs Committee's May 12 Hearing on Agent Orange Related Issues. Thomas A. Gasiewicz, Ph.D., Department of Biophysics, The University of Rochester, Rochester, New York, 14642.

Introduction. Comments on the written testimony submitted May 12 were made by representatives of the Environmental Protection Agency (Donald G. Barnes), the Office of Technology Assessment, the National Cancer Institute (Dr. Shelia Hoar Zahm), the Centers for Disease Control (Dr. James O. Mason), the Agent Orange Working Group, and the Veterans' Administration (Thomas E. Harvey).

General Comments. With the exception of some qualitative commmets (specifically discussed below), none of the representatives noted exception to any of the toxicological information that was presented in my testimony. Therefore, my responses will not directly deal with this information presented.

Many of the comments centered mainly around four basic issues discussed in my testimony: 1) the usefulness of previous data on exposed human populations, 2) the usefulness of future data on previously exposed human populations, 3) the significance of data on exposed experimental animals, and 4) the application of information from experimental animals to the problem of estimating the possible consequences to exposed human populations. The response of Donald Barnes (EPA) nicely summarized the intented thrust of my testimony, i.e.

"a. Ideally, risk assessment would be based on human data.
b. In the case of 2,3,7,8-TCDD, the human data base is not sufficient to generate a definitive risk assessment.
c. In the absence of such data, information from animals should be used.
d. More definitive information may be forth coming when "exposed" populations are more accurately characterized through the analysis of 2,3,7,8-TCDD in their tissues."

My responses will be based on these four points.

Specific Comments.

1. Environmental Protection Agency (Donald G. Barnes):

Like Don Barnes, I sincerely hope that the current studies in humans using isomer-specific analysis of tissues to assess exposure will "..shed some light on the sensitivity of humans to carcinogenic and immunological effects of 2,3,7,8-TCDD.", and I am in favor of the continued funding for these studies. However, it is possible that the results of these studies may be difficult to interpret for a number of reasons. Firstly, as results from tissue analysis are obtained, the actual number of individuals exposed to a significant amount of 2,3,7,8-TCDD may be much smaller than the original "exposed" population examined. This, severely limits the power of statistical analysis unless the effect is profound. Secondly, even within the identified exposed group there is likely to be a wide range of exposures. The establishment of exposure-response relationships with only a small number of individuals at each exposure level may be difficult. Finally, as noted in my original testimony, "...animal studies have noted that genetic differences may influence the degree of sensitivity towards dioxin. If this parameter influences human susceptibility, it would be even more difficult for epidemiological studies to discern a relationship between exposure and any particular adverse effect given the vastly diverse genetic nature of a given human population."

I am in agreement with all comments made by Don Barnes regarding my testimony. The comment (b) on the field of immunology is particularly appropriate and important. My brief original testimony should not be construed as indicating that in the case of dioxin the application of animal data to human risk assessment is a simple process. It certainly is not. Each particular effect, such as immunological, hepatic, etc., has to evaluated seperately and carefully taking all data into account before any conclusion, as tenuous as it may be, can be made. The point of this discussion in my original testimony was that we should not ignore the consistency of the effect of dioxin on the immune system in animals when attempting to determine possible human risks of exposure. Any further questions attempting to addressing what a particular dioxin-induced immune deficit in animals means specifically to any human effect is in need of much further evaluation by experts in that particular field.

2. Office of Technology Assessment:

The statement is made "Because 2,3,7,8-TCDD...is toxic to animals, it is, for public policy purposes, assumed to be toxic to humans.". In fact, all the evidence indicates that 2,3,7,8-TCDD is toxic to humans. No one doubts the evidence to indicate causality between 2,3,7,8-TCDD exposure to humans and the development of chloracne in these individuals. Although epidemiological studies have not shown clear causality between other effects and exposure, neither can they rule it out. Recently, a 10 member panel of experts in the area concluded that "Studies in animals suggest that the most likely adverse human health effects that might result from chronic exposure to PCDD/PCDFs would be cancer, adverse reproductive effects, and alterations in immune function. These effects have been demonstrated reproducibly in a wide range of animal species, but none have been found convincingly to occcur in humans.... Epidemiological studies, however, cannot rule out the possibility that adverse effects could occur in humans at exposures comparable to those that cause these effects in experimental animals. Limited experimental evidence from studies of human cells and tissues exposed...in vitro suggests that the responses are qualitatively similar to those produced in cells and tissues from experimental animals." (see footnote 1). The evidence, direct or indirect, is now beyond any assumptions. The questions now revolve around what particular effects will be observed in humans at what exposure levels. This representative of the Office and Technology Assessment even makes the statement that "...there is no reason to doubt that, under some conditions of exposure, it would also be toxic to human beings.".

In general, I agree with what may be viewed as a general conclusion from these comments that a number of qualifications should be placed on animal data in regards to their ability to accurately predict what would occur in humans. As I indicated in my original testimony "Ideally, information from exposed populations should be used.". Certainly even the best animal data will never replace good epidemiological studies. Furthermore, and as noted by the representative of the NCI, "...relying only on animal data can be misleading.". However, it is appropriate and reasonable that, in the absence of unequivocal human data, the consistencies of the animal data coupled with limited human data and experimental data using human tissues be utilized, with qualification, as a predictive guide to possible effects in humans. For example, from animal and human data there is at present no reason to suspect the presence of lesions in the cornea of dioxin-exposed humans. Chloracne is a common feature in exposed humans, and some, but not all, animal species show this disorder. On the other hand, tumor development and immune dysfunctions have consistently been observed in all mammalian species that have been tested. Although it is certainly possible humans may never show these effects, given the consistency of animal studies and a limited number of studies on human tissues, it seems more likely than not that humans, at some level of exposure, will show similar disorders. In the drug and chemical industries, animal data has been used for years in an attempt to predict the possible health risk and consequences to exposed humans for cases where human data is unable to be generated . Note that the results of animal studies do not and cannot establish that certain effects will occur or have occurred in exposed populations; but they do suggest that given certain circumstances of exposure, the occurrence of the particular effects in humans is more plausible.

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1 Human Health Aspects of Environmental Exposure to Polychlorinated Dibenzo-p-dioxins and Polychlorinated Dibenzofurans, a report of The Ad Hoc Panel on Health Aspects of Polychlorinated Dibenzo-p-dioxins and Polychlorinated Dibenzofurans, Universities Associated for Research and Education in Pathology, Inc., Bethesda,Maryland, June 1988.

3. National Cancer Institute (Dr. Shelia Hoar Zahm):

I believe that my testimony and above comments are in agreement with the statements made by the NCI representative.

4. Centers for Disease Control (Dr. James O. Mason):

Dr. Mason's comments regarding the use of animal studies have been addressed, in part, in my responses above. I agree with Dr. Mason that, in terms of dose and toxic effects, many of the toxic effects are very species specific. This I pointed out in my original testimony. Although these inconsistencies should not be ignored since they will likely provide important clues as to mechanisms and possible human effects, the consistent effects across all mammalian species tested are of concern. First of all the basic mechanism, i.e. receptor mediated, appears to be consistent across species. Since the mechanism involves modulation of gene expression, and we know that certain effects do occur in humans via this modulation (chloracne, enzyme induction), the likelihood is high that other effects, as some dose level, are likely to occur. Furthermore, and regardless of the different types of effects observed, all mammalian species tested show multiple effects and not just a single one. Since certain effects, such as immune suppression, occur in all species tested, it is reasonable to deduce that this may also occur in humans. All of this relies on deductive reasoning based on animal data, and certainly there is at present no firm evidence to indicate that immune suppression occurs in exposed human. However, nor is there evidence to rule out the possiblilty.

Since the publication of the document by the Review Committee of the American Academy of Clinical Toxicology (*Clinical Toxicology* 23, 195, 1985) much more data has come out regarding the toxicology of dioxin in different species. In the past few years there have been more and more results indicating that for certain toxic effects the relative sensitivities are quite similar. For example, Dr. James Olson (University of Buffalo) will be presenting data at the Society of Toxicology meeting in Atlanta (March, 1989) indicating striking similarities of the developing fetus in both hamster and rat to the teratogenic effects of 2,3,7,8-TCDD[2]. Yet, in terms of the lethal dose to adult animals, the sensitivity difference between these species is more than 50-fold. Again, for a more recent assessment of the animal and human data I refer to the review by a panel of experts in this area (see section directed to the Office of Technology Assessment above and footnote 1).

For comments regarding the interpretation of health studies in progress see the above section directed to the Environmental Protection Agency.

5. Agent Orange Working Group:

Since the comments from this group are the same (word for word) as that from the Centers of Disease Control, the latter section should be referred to.

6. Veterans' Administration (Thomas E. Harvey):

Mr. Harvey correctly points out that what may be logical is not necessarily unequivocal. In order to make a complete and unequivocal statement regarding human health effects of dioxins, sound and complete studies designed to get at dose-response relationships need to be conducted. The past epidemiological studies, because of lack of exposure assessment and a variety of other reasons, are not sufficient to be definitive. Studies presently being conducted may be more useful, but there are still likely to be a number of difficulties, as cited above. Thus, since we cannot purposefully dose humans with 2,3,7,8-TCDD, it is unlikely that an unequivocal study will ever be conducted. However, most of the animal data on 2,3,7,8-TCDD are unequivocal and based on sound, valid scientific studies. Certainly, the extension of animal data to humans is not without difficulty, and it alone cannot give uniquivocal answers regarding human health effects. In this I am in complete agreement. However, in the absence of good human data, "...it is scientifically sound and appropriate that any human health risk assessment of dioxins consider the wealth of information available from animal studies." (see text of my original testimony).

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[2] personal communication, Dr. James Olson, Department of Pharmacy and Therapeutics, State University of New York at Buffalo, Buffalo, New York.

As I have noted in my original testimony, Mr. Harvey also correctly points out that "There is not, at present, any credible evidence that humans exposed to dioxin or to Agent Orange or any of its components suffer suppression of the immune system as a consequence of that exposure.". However, there is certainly no credible evidence to dismiss the possiblity. The studies that Mr. Harvey sites offer no actual exposure assessment.

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